

HumaVision

| User Manual



CE

REF 17660/1

REVISION

REVISION LIST OF THE MANUAL

Rev./DATE	REVISION DESCRIPTION
01/2024-11	First Edition

SYSTEM VERSION

COPYRIGHT

Copyright 2024, HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Wiesbaden, Germany. All rights reserved.

No part of this documentation may be reproduced in any form, nor processed, copied or distributed by means of electronic systems, without prior permission of HUMAN in writing. Since all precautionary measures were taken into account in producing these operating instructions, the manufacturer accepts no responsibility for any errors or omissions. This includes any liability for damage that could arise from possible incorrect operation based on this information. Subject to changes without notice as result of technical development.

SERVICE AND SUPPORT

CONTENTS

TABLE OF CONTENTS

1 SAFETY INSTRUCTIONS	9
1.1 INTRODUCTION	9
1.2 USER WARRANTY	9
1.3 USE OF THE INSTRUMENT	10
1.4 GENERAL SAFETY WARNINGS	10
1.4.1 Electromagnetic considerations	11
1.4.2 Lithium polymer battery	13
1.4.3 Radio communications	14
1.5 DISPOSAL MANAGEMENT CONCEPT	15
1.6 BIOHAZARD WARNING	16
1.7 INSTRUMENT DISINFECTION	16
1.8 SYMBOLS	17
2 SYSTEM DESCRIPTION	19
2.1 INTENDED PURPOSE	19
2.2 INTRODUCTION INTO DIGITAL HOLOGRAPHIC MICROSCOPY	19
2.2.1 Image acquisition and hologram retrieval	20
2.2.2 Image reconstruction	22
2.3 PRODUCT SET COMPONENTS	23
3 SET UP	25
3.1 PLACEMENT AND USE	25
3.2 INITIAL SETUP	25
3.3 CHARGING THE BUILT-IN BATTERY	26
3.4 SWITCHING ON THE INSTRUMENT	27
3.5 SWITCHING OFF THE INSTRUMENT	29
3.6 EXITING ENERGY-SAVING MODE	30

4 CARRYING OUT MEASUREMENTS	31
4.1 PRELIMINARY REMARKS	31
4.2 SAMPLE HANDLING	33
4.2.1 General remarks	33
4.2.2 Sample preparation guide	34
4.2.3 Optional sample preparation	36
4.3 MEASURING PROCEDURE	36
4.4 MICROSCOPY RESULTS USING HUMAVISION (FOR INVESTIGATIONAL USE ONLY)	42
4.5 WEEKLY MAINTENANCE	43
4.6 DATABASE	44
4.7 MICROSCOPY OF URINE SAMPLES WITHOUT USING HUMAVISION	47
4.8 QUALITY ASSURANCE	49
4.8.1 Microscope sensor check	49
4.8.2 Refresh sensor data	52
4.8.3 Quality control	53
5 SETTING UP THE HUMAVISION	55
5.1 SETTINGS MENU	55
5.2 CONFIGURATION OF THE WLAN ADAPTER	56
5.2.1 Description of Operating Modes	56
5.2.2 WLAN mode	58
5.2.3 Hotspot mode	59
5.2.4 Offline mode	60
5.3 SOFTWARE UPDATE	61
5.4 LANGUAGE SETTINGS	63
5.5 TIME AND DATE SETTINGS	64
5.6 DISPLAYING SYSTEM INFORMATION	64
5.7 CONNECTIVITY FOR PDF EXPORT	65
5.8 CUSTOMIZE THE PRINTOUT OR PDF FILE	66
5.9 PROVIDE SUPPORT DATA	67

CONTENTS

6 OPERATING AND MAINTENANCE INSTRUCTIONS	69
6.1 PROHIBITIONS ON USE	69
6.2 SERVICE LIFE	69
6.3 USAGE LOCATION	70
6.4 CLEANING	70
6.4.1 External cleaning	71
6.4.2 Cleaning the sensor and measuring chamber	72
6.5 TRANSPORTATION/ STORAGE	76
6.6 DECOMMISSION	76
6.7 DISPOSAL	76
7 TECHNICAL SPECIFICATIONS	79
7.1 HUMAVISION SPECIFICATIONS	79
7.2 ACCESSORIES	81

1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid damage to the instrument or personal injury, carefully read the "GENERAL SAFETY WARNINGS" describing the appropriate operating procedures. Please contact the technical Service in the event of instrument failure or other difficulties with the instrument.

1.2 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item within this warranty period at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

1.3 Use of the Instrument

The instrument must be used for its intended purpose (see chapter 2.1 Intended Purpose). It must be operated in perfect technical conditions, by qualified personnel, in such working conditions and maintained as described in this manual, in the GENERAL SAFETY WARNINGS. This manual contains instructions for qualified professional operators.

1.4 General Safety Warnings

Use only accessories specified and supplied by HUMAN and/or mentioned in this manual. Place the product so that it has proper ventilation. The instrument should be installed on a flat, stationary working surface, that is free of vibrations.

Do not operate in area with excessive dust. Operate at temperature and at a humidity level in accordance with the specifications listed in this manual, see chapter 7.1.

Do not operate this instrument with covers and panels removed. Use only the power cord specified for this product. To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power the instrument in environments that are potentially explosive or at risk of fire.

Prior to cleaning and/or performing maintenance on the instrument, switch off the instrument and remove the power cord. Only cleaning materials described in this manual may be used, as other materials may damage parts. It is recommended to always wear protective clothing and eye protection while using this instrument. All warning symbols that appear in this manual must be carefully observed.

Care must be taken not to spill any liquid over the instrument or insert any objects through openings.

The user shall not repair the instrument themselves.

For users in the European Union only: Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

1.4.1 ELECTROMAGNETIC CONSIDERATIONS

The instrument is intended for use in a basic electromagnetic environment. Do not operate the instrument in the immediate vicinity of other devices, with other devices in stacks, or in proximity of strong electromagnetic radiation (e. g. unshielded intentional RF sources), as this could result in incorrect functioning. The use of accessories or cables other than those specified by the manufacturer may lead to increased electromagnetic interference or reduced electromagnetic immunity of the instrument and could result in incorrect functioning.

Portable RF communication instruments (mobile phones, radios) should not be used at a distance of less than 30 cm from the instrument. Failure to observe this instruction may lead to a reduction in performance. The instrument has been tested in accordance with EN IEC 61326-1:2021, EN IEC 61326-2-6:2021 and ETSI EN 301 489-17 V3.2.4. The instrument is not known to cause any interference. Despite testing, a deterioration in EMC behavior (transmission and reception) may occur, e. g., as a result of aging or failure of assemblies. In such cases, the instrument must be checked at the manufacturer's premises.

HumaVision is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

Unforeseen interference from the instrument may occur if the level of interference exceeds the levels required by EN IEC 61326-1:2021, EN IEC 61326-2-6:2021 and ETSI EN 301 489-17 V3.2.4. This may occur as a result of the choice of installation site, e.g., amplification of existing sources of interference.

The users are advised to evaluate the electromagnetic environment prior to operation of the instrument to avoid any deterioration in the performance of the instrument.

In this event, the operator should position the instrument in such a way as to minimize any interference.

The instrument has been tested in accordance with EN IEC 62311:2020 and EN 62479:2010. The instrument is not known to expose the user to any electromagnetic radiation above the level of the basic restrictions for general public exposure specified by these standards.

1.4.2 LITHIUM POLYMER BATTERY

The instrument is equipped with a lithium polymer battery, which has been tested in accordance with IEC 62133-2:2017. Improper use of the battery may lead to a reduction in battery life. To avoid irreversible capacity losses, observe the following principles:

The optimum temperature range is 18-25 °C.

! Note: Only charge the battery in the specified nominal operating range (see chapter 7)! Failure to observe this instruction may result in permanent damage to the battery, or may cause the battery to act as a source of ignition.

Avoid fully discharging the battery. A lower charge cycle depth (starting the charging process before a 100 % discharge) will increase the battery's service life.

If storage is necessary, aim for a remaining battery capacity of 30 % to 40 %. Temperatures should be below room temperature (approx. 18-25 °C). To avoid excessive discharge, the battery should be charged to at least 40 % once every six months.

! Note: Lithium batteries do not exhibit a memory effect.

The battery should only be replaced by the local distributor. Return the instrument to the local distributor only in a discharge state.



WARNING



Electrical hazard

Many chargers consume power while they are plugged into the socket - even if they are not charging. Disconnect the charger from the mains after charging.

1.4.3 RADIO COMMUNICATIONS

The instrument has been tested in accordance with ETSI EN 300 328 V2.2.2. The user should only connect the instrument to trusted wireless networks (WLAN) that are protected from unauthorised access through the internet by the use of firewalls. Always make sure that the data is shared and received only with instruments that are trusted and properly secured.

Obstacles (e.g., walls, fences, grates) located between the instrument and the devices to which it is connected (e.g., WLAN routers, computers with WLAN) may reduce the maximum range of the WLAN connection.

Furthermore, a decrease in the data transfer rate may be expected in such cases. HUMAN is not responsible for the loss, interception or misuse of data sent or received when using the instrument's wireless communication methods.

1.5 Disposal management concept

The applicable local regulations governing disposal must be observed. It is the user's responsibility to arrange for proper disposal of the individual components.

All parts which may contain potentially infectious materials must be disinfected by suitable, validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal must be carefully observed. The instruments and electronic accessories must be disposed of according to the applicable local regulations for the disposal of electronic components.

Batteries, power packs and similar power sources must be removed from electric/electronic parts by the Technical Service of the local distributor and disposed of in accordance with applicable local regulations.

1.6 Biohazard warning

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious. For safety reasons, we have labelled the instrument with the "BIOHAZARD" warning label below.

FIGURE 1

Biological hazard symbol



1.7 Instrument disinfection

Before performing any servicing on the instrument, it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. Decontamination must be performed by authorised well-trained personnel, and in observance of all necessary safety precautions.

1.8 Symbols












When you see...	It means...
	Weight
	Dimensions
	Follow the instruction in the manual related to the symbol to avoid potential biocontamination.
	Follow the instruction in the manual related to the symbol to avoid personnel injury. Follow the instruction in the manual related to the symbol to avoid analyzer damage and failure, or unreliable analysis results.
	Follow the instruction in the manual related to the symbol. The symbol highlights the important information in operating procedures that calls for special attention.
	For in vitro diagnosis only
	Serial No.
	European CE declaration of conformity
	Date of manufacture
	Manufacturer
	Storage temperature

TABLE 1



Humidity level for storage



Atmospheric pressure level for storage



Consult the user manual

2 SYSTEM DESCRIPTION

2.1 Intended purpose

HumaVision is a digital semi-automated urine microscope. It is intended to acquire holographic images of different cell types and microorganisms in human urine samples for the qualitative human urine examination. It is used as an aid to diagnosis of the general health status. For laboratory professional use only.

HumaVision is intended to be used with the specified Urine Sample Carrier HumaVision (REF 17661).

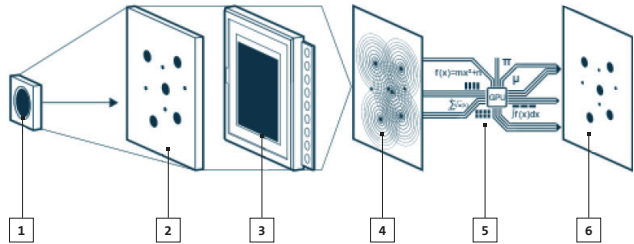
2.2 Introduction into digital holographic microscopy

Digital holographic microscopy (DHM), an innovative combination of holography and microscopy, is revolutionizing urine microscopy analysis. This cutting-edge imaging technique offers a label-free and high-resolution approach to visualize microscopic objects in three dimensions. Unlike traditional microscopy, DHM does not require staining of the urine sample, preserving its integrity, and providing more accurate results.

The essence of DHM lies in its ability to capture both the intensity and phase information of coherent light interacting with the microscopic objects in the urine sample. This quantitative phase imaging enables researchers and medical professionals to gain valuable insights into the cellular structures, thickness variations, and optical properties of the objects being examined.

FIGURE 2
Principle of digital holographic microscopy (DHM)

- 1 LED
- 2 Sample
- 3 CMOS (sensor)
- 4 Raw image
- 5 Digital image reconstruction
- 6 Image



2.2.1 IMAGE ACQUISITION AND HOLOGRAM RETRIEVAL

Sample preparation is the essential initial step before image acquisition. During this step, homogenize the urine sample, transfer it to a slide, and then introduce it to the HumaVision.

Next, the sample on the slide is illuminated with a LED which has a constant phase relationship between its waves. This results in a stable and predictable interference pattern when it interacts with the microscopic objects in the sample.

As the coherent light passes through the urine sample, it interacts with the microscopic objects in the urine, such as cells, bacteria, crystals, and other cellular components. These microscopic objects diffract the light, causing it to change direction and create complex interference patterns.

The interaction of the coherent light with the microscopic objects causes a phase shift in the light waves. The phase shift represents the variations in the optical path length caused by the presence of different objects in the sample.

The phase-shifted light waves, along with the unaltered reference light (beam that does not interact with the sample), combine to form an interference pattern known as a hologram. This hologram is a complex pattern that contains information about both the amplitude and phase of the light waves at each point in the sample.

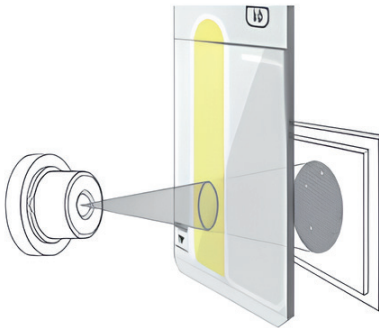


FIGURE 3

HumaVision microscopic
image by LED

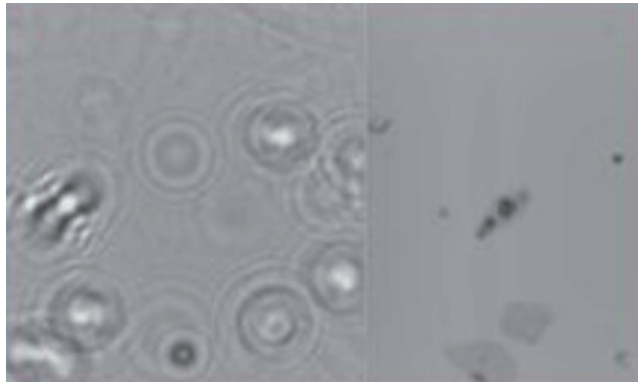
A photosensitive sensor is used to record the hologram. It captures the intensity of the interference pattern across the entire field of view, effectively capturing the information about the interactions between the coherent light and the microscopic objects.

2.2.2 IMAGE RECONSTRUCTION

The captured hologram contains valuable information about the particles present in the urine sample. The image reconstruction involves converting the hologram back into a recognizable image of the microscopic objects. Specialized mathematical algorithms are used to analyze the hologram and reconstruct the image of the microscopic objects. These algorithms use the principles of diffraction and interference to decode the information contained in the hologram.

FIGURE 4

Microscopic image before
and after reconstruction



2.3 Product set components

TABLE 2

No.	Name	REF	Description
1	HumaVision	17660	Instrument for urine microscopy
2	Technical documentation	17660/1	User manual
		17660/2	Quick guide
		17660/3	Dilution guide
3	USB battery charger	17660/105	See chapter 7.2 Accessories
4	USB-C cable	17660/106	See chapter 7.2 Accessories
6	Sample carrier holder key	17660/100	Tool for removing the sample carrier holder (for cleaning)
7	Sample carrier holder (built-in)	17660/101	Sample carrier holder (inserted in the instrument; to be removed only during cleaning)

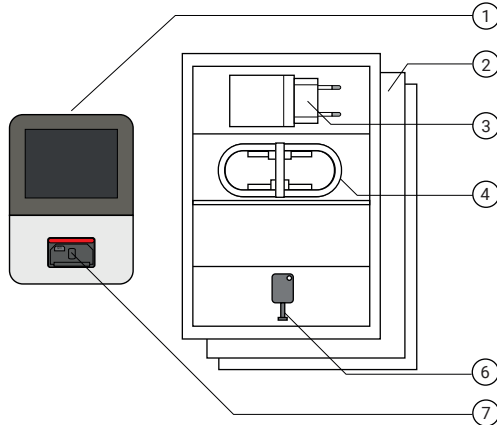


FIGURE 5

HumaVision product set components

! **Note:** Check that the product set is complete, based on the delivery note. Use only products and accessories that have no defects. Report any damage to HUMAN's Service department immediately.

- ! **Note:** Note the full part number as specified on the delivery note for your orders.

Accessories

TABLE 3

No.	Name	REF	Description
1	Urine Sample Carrier HumaVision	17661	Slide used for the measurements (microscopy)
2	Cleaning Sticks HumaVision	17662	Set of 12, see chapter 6.4.2 Cleaning the sensor and measuring chamber

3 SET UP

3.1 Placement and use

HumaVision is a compact portable instrument that can be carried with one hand. For measurements, the HumaVision shall be placed on a flat and stationary working surface, that is free of vibrations.

! Note: During the analysis, keep the instrument still.
● Place the instrument stationary on a stable surface and protected from direct sunlight.

3.2 Initial setup

! Note: On delivery, the HumaVision is in shipping mode. To start HumaVision for the first time, connect it to the supplied USB charger using the supplied USB cable, then the HumaVision automatically turns on.

1. Remove the protective film from the instrument's display by holding the small tab and carefully pulling it off downwards over the display.
2. Connect the instrument to the supplied USB charger, the USB cable, and a mains socket – the same procedure as when charging the battery (see chapter 3.3 **Charging the built-in battery**).
3. The power button lights up briefly. The instrument is no longer in shipping mode and can be switched on (see chapter 3.4 **Switching the instrument on**).

3.3 Charging the built-in battery



WARNING

Hot surface

While charging, place the HumaVision on a stable, level, fire-resistant surface. The charging process may cause the bottom of the HumaVision to heat up.

! **Note: Charge and operate the HumaVision only with the supplied power supply unit described in the specifications (see chapter 7 Technical Specifications).**



WARNING

Electrical hazard

Only charge the battery in the specified nominal operating range (see chapter 7.1 **HumaVision specifications**)! Not following this instruction can cause permanent battery damage or may cause the battery to act as a source of ignition.

1. Place the HumaVision on a stable, level, secure, fire-resistant surface.
2. Plug the supplied USB charger into a mains socket.
3. Plug the USB Type-A connector of the USB cable into the USB port on the USB charger.
4. Plug the USB Type-C connector of the USB cable into the USB port on the HumaVision.
5. The charging process is active when the power button on the HumaVision lights up at regular intervals.

6. The battery is fully charged when the power button stops lighting up at regular intervals or when the battery icon on the display is full.
7. Disconnect the USB charger from the instrument when the battery is fully charged. First unplug the connector on the USB cable from the instrument before unplugging the power supply unit from the mains socket.

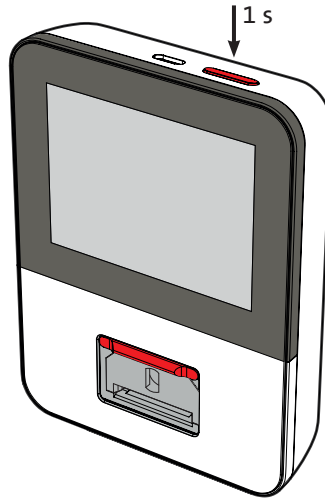
! Note: The HumaVision can be switched on and used for measurements during the charging process. It is not necessary to wait until the battery is fully charged to switch the instrument on.

3.4 Switching on the instrument

! Note: In order to be able to switch on the HumaVision, either charge the instrument's battery (partially or fully) or connect the USB charger to the instrument (see chapter 3.3 Charging the built-in battery).

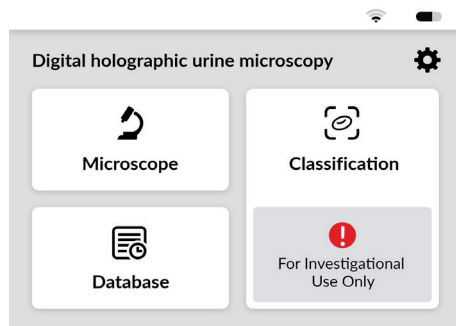
1. Switch on the HumaVision by pressing and holding the power button for about one second.

FIGURE 6
Switching on
the HumaVision



2. Wait for the instrument to start, which takes about 40 seconds. The start-up is complete when the main menu (see Figure 7) appears on the display. The HumaVision is now ready for operation.

FIGURE 7
Main menu of HumaVision



3.5 Switching off the instrument

! **Note:** There are several possible ways to switch off the HumaVision. For fault-free operation of the HumaVision, use a “normal shutdown”. If a “normal shutdown” is not possible (e.g., as a result of a non-responsive instrument), select [error shutdown].

Normal shutdown (recommended):

1. Press and hold the power button on the HumaVision for approx. one second until a selection menu (“Shut down the instrument – Yes/ No”) appears on the display.
2. Tap [Yes] to turn off the instrument. Tap [No] to cancel the process. The instrument is switched off when the power button is no longer illuminated.

Error shutdown (not recommended):

1. Press and hold the power button for about 8 seconds until the LED flashes faster.
2. This immediately turns off the instrument. Under certain circumstances, this may result in data loss of the most recent measurements.

! **Note:** Only use this procedure if a “normal shutdown” (see above) is not possible.

3.6 Exiting energy-saving mode

! **Note:** The HumaVision has an energy-saving function.

- **First, it dims the display after a set period of inactivity. Then it turns off the backlight to enter energy-saving mode. Apart from the display of the graphical user interface, the HumaVision is fully functional in this mode.**

Energy-saving mode:

- Automatically activates after 2 minutes of inactivity.
- Display is dimmed for a brief period and then switched off.
- Power button lights up cyclically (“breathing”).

To exit power-saving mode and return the instrument to the active state, tap on the touch screen.

4 CARRYING OUT MEASUREMENTS

4.1 Preliminary remarks

If the HumaVision or the Urine Sample Carriers have been stored at an ambient temperature $\leq 5\text{ }^{\circ}\text{C}$, they must be unpacked and allowed to adjust to room temperature before measurements are carried out. The instrument's cover must be closed all the time when no measurement is taking place. Otherwise, dust can enter the measuring chamber and damage the sensor.

! Note: Use the HumaVision only with the suitable Urine Sample Carrier and the sample carrier holder. Other slide types do not work and can give wrong results or no results. Do not try to insert different slides, this can damage the instrument.



WARNING



Biohazard

Always wear gloves when working with Urine Sample Carrier to avoid any potential hazards, e. g., contamination with infectious material.

The instrument is a standalone unit, ready for immediate use. Users can do all required operations via the touch screen interface. The touch screen displays measurement results as well.

! Note: If the user stops or aborts a measurement before it is complete, an immediate remeasurement is not possible.

FIGURE 8
Main menu of
HumaVision

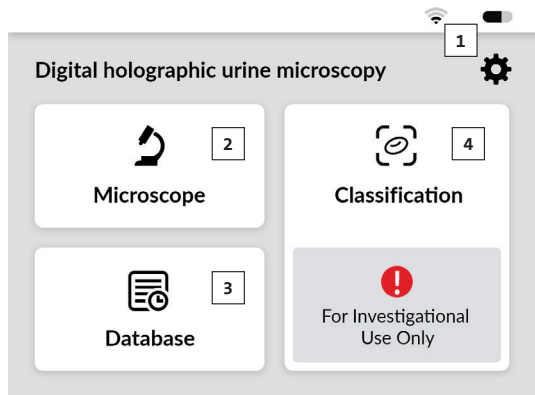


TABLE 4

Item no.	Name	Description
1	Main bar	Contains icons for WLAN status and battery status
2	Microscope	Starts a new microscopic image of the urine sample
3	Database	List of completed images/measurements
4	Classification	Automated classification and counting of urine particles. This application is not yet intended for in vitro diagnostic purposes but for investigational use only. For more information about this function, please request the document "HumaVision - Urine Sediment Parameters" from HUMAN's Service department.

4.2 Sample handling

4.2.1 GENERAL REMARKS

- Sample source: The HumaVision is used to take microscopy images of human urine samples.
- Carry out the measurement within the first 2-6 hours after sample collection (see Kouri TT, Hofmann W, Falbo R, Oyaert M, Schubert S, Gertsen JB, Merens A, Pestel-Caron M; Task and Finish Group for Urinalysis (TFG-U), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). The EFLM European Urinalysis Guideline 2023. Clin Chem Lab Med. 2024 Jun 5;62(9):1653-1786. doi: 10.1515/cclm-2024-0070. PMID: 38534005).
- During the measurement, the sample should be at room temperature (18-25 °C).

If the sample can't be processed within the recommended time frame, the sample should be refrigerated to preserve cellular content. This can lead to crystal formation, thus, crystal particles shall be excluded from the analysis.


! Note: Check the condition of the sample before the measurement. If there is any turbidity or if the sample is too colored (red), follow the steps for sample preparation described in chapter 4.2.3 Optional sample preparation.

If the density or impurity is too high, it is recommended to dilute the sample according to the Dilution Guide (REF 17660/3).

4.2.2 SAMPLE PREPARATION GUIDE

The Sample Preparation Guide assists in executing all crucial pre-analytical steps. It helps to understand instrument operation to achieve accurate analysis results.

To use the Sample Preparation Guide:

1. On the HumaVision main menu navigate to “Microscope”.
2. Tap on the “Sample preparation guide” button .

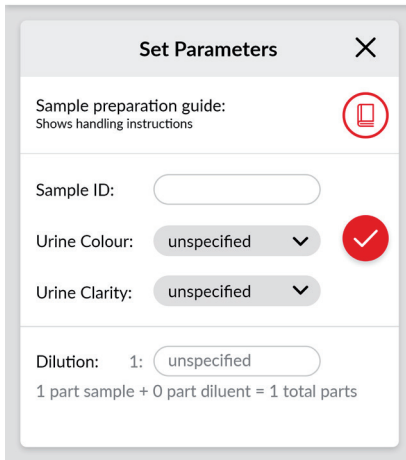


FIGURE 9

Set sample parameters

3. Tap on  to move forward through the pages.

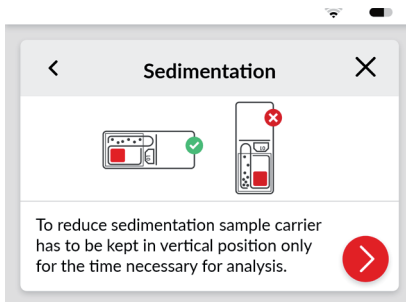


FIGURE 10

Sample carrier should be kept in vertical position only for the time necessary for the analysis.

4. Tap on [**<**] to move backward through the pages.
5. Tap on [**X**] to close the guide.

4.2.3 OPTIONAL SAMPLE PREPARATION

In special cases, it is required to dilute samples in the laboratory before performing an analysis.

For a reliable measurement, a urine volume of at least 0.5 ml is required.

Highly turbid or colored urine samples should be pre-diluted, using the Dilution Guide (REF 17660/3).

4.3 Measuring procedure

1. Open the cover of the measuring chamber (red lid).

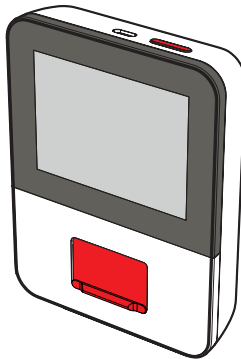


FIGURE 11

Closed measuring chamber

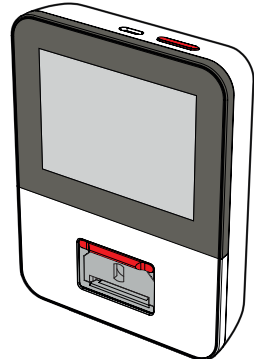


FIGURE 12

Opened measuring chamber

2. Make sure the sample carrier holder is correctly placed in the measuring chamber. If unsure, use the sample carrier holder key to remove it. Then re-insert the sample carrier holder into the measuring chamber until it clicks into place.

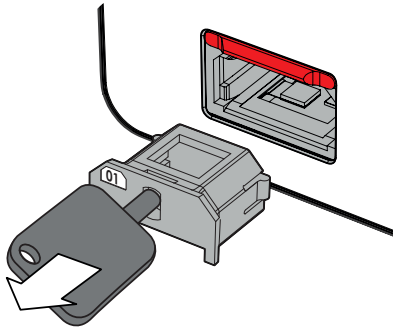


FIGURE 13
Removing the sample carrier holder with the key

3. From main menu navigate to “Microscope”.

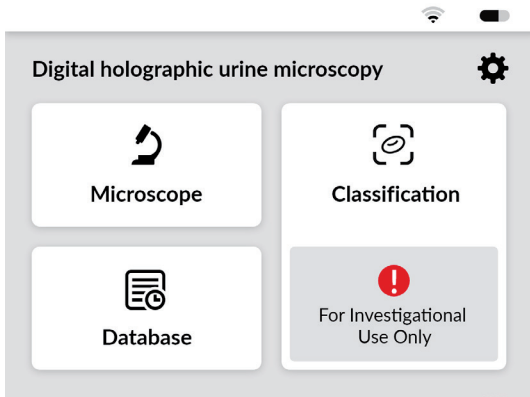



FIGURE 14
Main menu of HumaVision

4. Set each sample parameter. Confirm by tapping the confirmation button . The following parameters can be modified:
 - Enter a unique sample ID.
 - Enter sample color from predefined list.
 - Enter sample clarity from predefined list.
 - Enter sample dilution if the sample was diluted before analysis.
 - The sample dilution is entered in a format of a dilution factor: 1:X, means 1 part of sample (fixed value) in X parts of total volume.
 - The dilution ratio is displayed as a part of result report and is used for automatic recalculation of the result as well.

5. Take a Urine Sample Carrier from the supply box. Touch only the lower part of the Urine Sample Carrier.

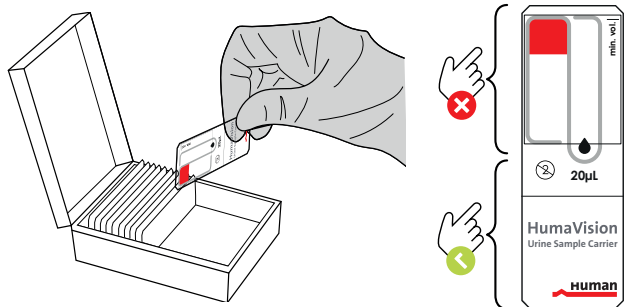
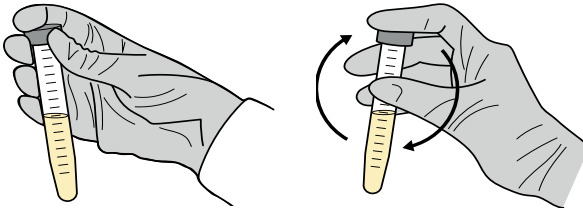


FIGURE 15

How to touch the Urine Sample Carriers

- The sample must be thoroughly homogenized by inverting the tube filled with urine sample ten times.

**FIGURE 16**

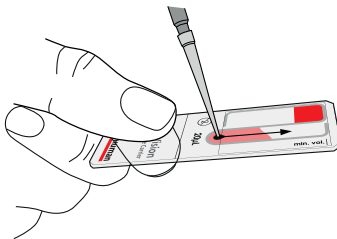
Inverting the urine sample

- Aspirate 20 μl from the lower third of the sample.

**FIGURE 17**

Aspiration of sample volume

- Dispense the sample (20 μl) on the marked area of the Urine Sample Carrier. Make sure there are no air bubbles in the pipette tip, as this leads to incorrect results.

**FIGURE 18**

Dispensing the sample onto the sample carrier

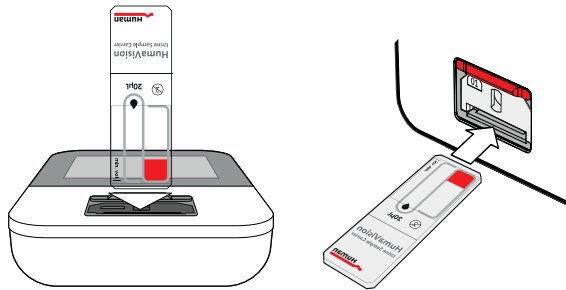
! Note: Chapter 4.2 Sample handling contains important instructions for sample preparation.

9. Insert the Urine Sample Carrier into the slot on the HumaVision. Measure the urine right after filling the Urine Sample Carrier. This avoids errors from sample evaporation.

FIGURE 19

Inserting the sample carrier into HumaVision

! Note: If the instrument detects that the Urine Sample Carrier is missing, misaligned or unauthorised, the measurement will not start. After 30 seconds the following message is displayed: "No sample carrier inserted! Do you want to continue? - Cancel/Continue".



10. The measurement starts automatically, when the Urine Sample Carrier is inserted correctly. This may take 1 to 4 minutes, depending on the density of the sample.

FIGURE 20

Microscopic image process taking place



11. The results are shown on the display.

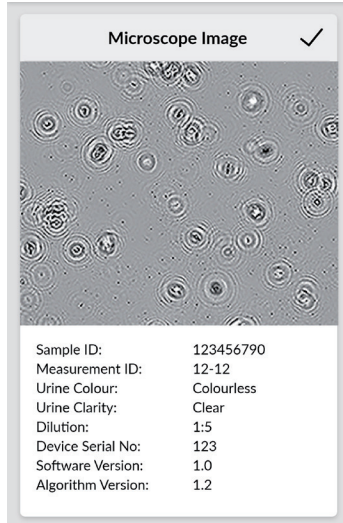


FIGURE 21
Result of
microscopic image

12. The measurement results can be saved in internal memory (see chapter 4.6 Database).

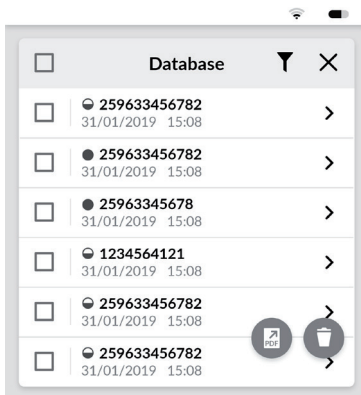


FIGURE 22
Database of
microscopic images

13. After the measurement, close the cover immediately. Otherwise, dust can enter the measuring chamber and damage the sensor.

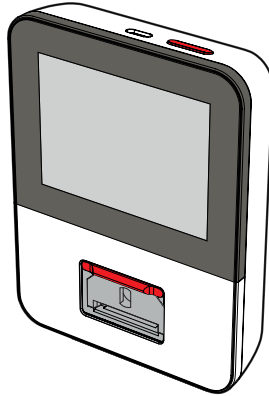


FIGURE 23
Opened measuring chamber

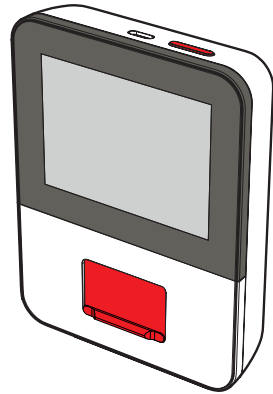


FIGURE 24
Closed measuring chamber

4.4 Microscopy results using HumaVision (For Investigational Use Only)

After the measurement, the microscopic image is displayed. When clicking the button “For Investigational Use Only” from the main menu, more information beside the microscopic image is displayed. This application is not yet intended for in vitro diagnostic purposes but for investigational use only. For more information about this function, please request the document “HumaVision - Urine Sediment Parameters” from HUMAN's Service department.

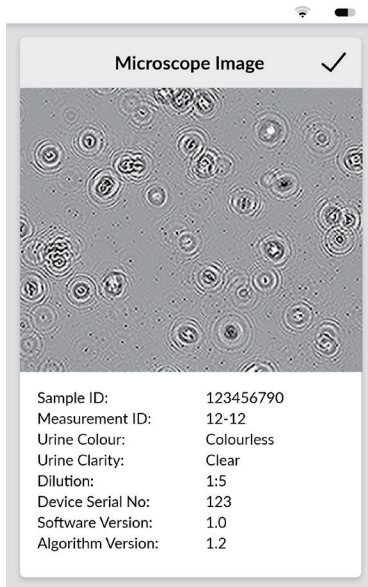


FIGURE 25

Result of microscopic image

4.5 Weekly maintenance

The cover must be closed all the time when no measurement is taking place. Otherwise, dust can enter the measuring chamber and damage the sensor. Dust particles are too small to be seen by eyes. Clean the sensor only with very clean swabs to avoid scratching and damaging it.

Only the Cleaning Sticks HumaVision (REF 17662) should be used to clean the HumaVision sensor. The use of any other sticks is not recommended, and any potential harm caused thereby is not the responsibility of HUMAN. The Cleaning Sticks are for single use only.

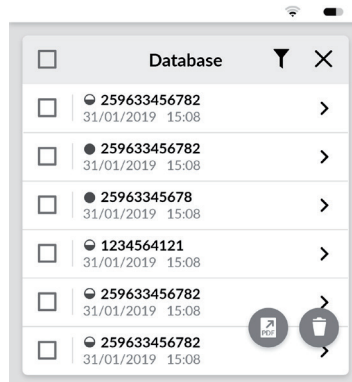
The measuring chamber should be cleaned weekly in order to maintain the HumaVision's measuring performance.

Follow the detailed steps of the cleaning procedures described in chapter 6.4 **Cleaning**.

4.6 Database

The Database (history) function of the HumaVision contains all the saved measurements (microscopic images). They can be sorted, filtered, deleted, and called up by tapping on the given item from the list. The measurement can be sorted by sample ID or time and date of measurement.

FIGURE 26
Database of microscopic
images



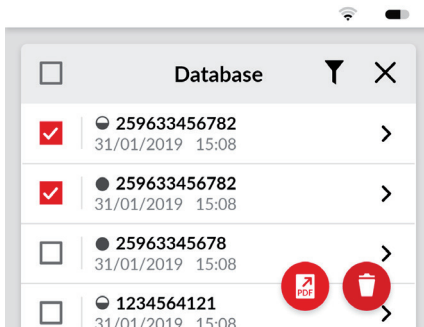
Filter

The Filter function allows to display only those measurements with a specific sample ID, measurement date and time, and a positive or negative result of selected categories. Then, only results that match the filter specification are displayed.

Printout solution: Exporting the results as PDF file

After taking the measurement (microscopic image), the result can be exported as a PDF file. From main menu navigate to “Database”.

1. From the listed data in “Database”, select the respective document from which the printout/PDF is to be created.
2. Press the button “PDF”.

**FIGURE 27**

Selecting results in the Database

3. Creating the PDF file takes a short time, indicated by the following screen.

FIGURE 28

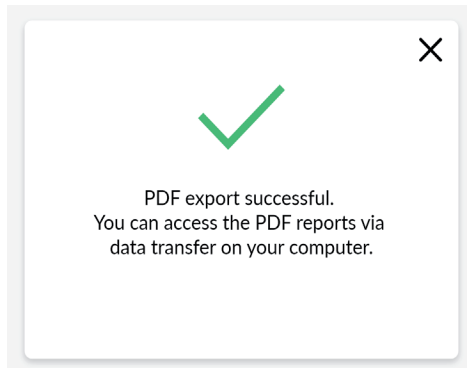
Microscopic image process
taking place



4. The measurement results are then accessible on the computer as PDF file.

FIGURE 29


PDF export successful




In case this function is not available, check the “Connectivity for PDF export” in the settings (chapter 5.7 **Connectivity for PDF export**). There is the possibility to add a laboratory name on the PDF, see chapter 5.8 **Customize the print-out or PDF**.

Delete measurements

HumaVision allows to delete either one or multiple measurements from the Database.

1. Select the checkboxes of all items to be deleted from the Database.
2. Tap on the Delete icon  .

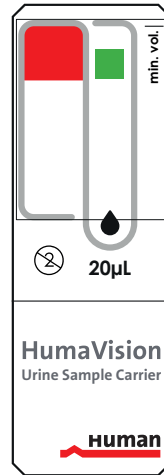
To delete the entire measurement history, tap the top checkbox to select all items, then tap the Delete icon  .

! **Note:** To prevent data loss, make sure to do a backup of the data before deleting the whole Database.

4.7 Microscopy of urine samples without using HumaVision

In addition to being used with the HumaVision, for specific issues, the Urine Sample Carrier can also be used with a conventional microscope. This is useful for manual classification of non-classified crystals, confirming bacteria presence, or more precise cell characterization. In this case, the same Urine Sample Carrier can be examined under the microscope immediately after analysis in the HumaVision.

FIGURE 30
Urine Sample Carrier



Apply the Urine Sample Carrier to the stage of a suitable laboratory microscope. Point the lens at the area marked in green color in Figure 30. After manually focusing on the focal plane, it is possible to display objects contained in the urine. Note that during analysis in the HumaVision, the Urine Sample Carrier is vertical and there is slow sedimentation of the cells and particles in the urine. This means that manual follow-up check should be carried out immediately after analysis in the HumaVision.

The Urine Sample Carrier should be used exclusively with an intact liquid film in the sample chamber. If it has dried out, the Urine Sample Carrier can no longer be used for analyses and should be discarded. In addition, the Urine Sample Carrier is not suitable for storing samples.


Ensure a clean working procedure with the Urine Sample Carrier, so that neither the sample nor the Urine Sample Carrier is contaminated. Follow these instructions to avoid false positive results.

4.8 Quality assurance

If the instrument's sensor is not working properly, check the microscope sensor's status and refresh it if needed.

4.8.1 MICROSCOPE SENSOR CHECK

Checking the sensor status is a quality control procedure for maintaining the HumaVision's measuring functionality and resolution.

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the menu item [Maintenance].
3. Tap on the menu item [Microscope sensor check].

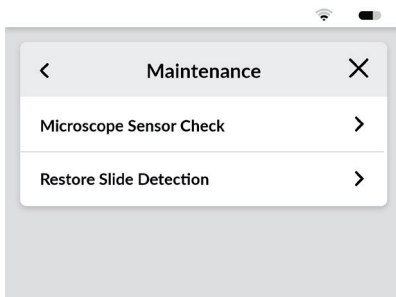
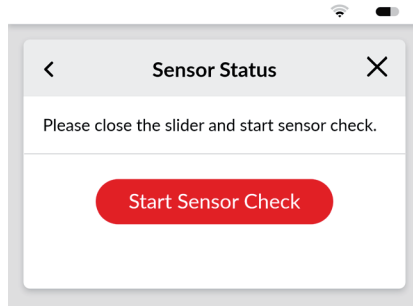


FIGURE 31

Maintenance screen

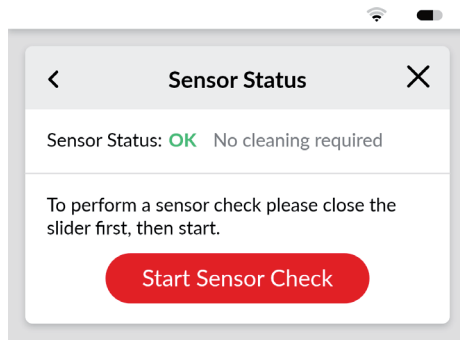
4. Tap on [Start sensor check].

FIGURE 32
Sensor status before
starting the check



5. After a few seconds, the result of the sensor check appear underneath the green button.

FIGURE 33
Sensor status "OK"



6. If the status is “OK”, no further action is required. In all other cases, clean the sensor (see chapter 6.4 **Cleaning**).

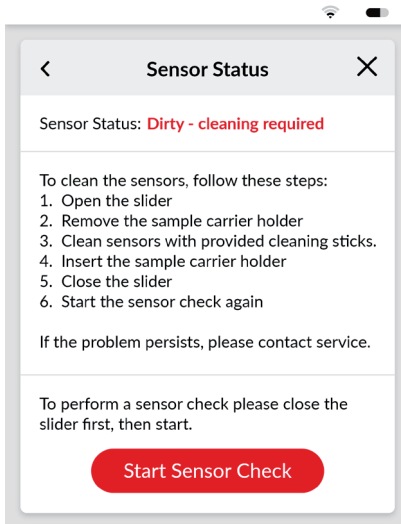


FIGURE 34
Sensor status "Dirty" -
cleaning required

! **Note:** The HumaVision can only be used for further measurements if the sensor status “OK” is displayed. If the sensor status does not show “OK”, even after repeated cleaning of the sensor, stop using the HumaVision and contact the HUMAN Service.

4.8.2 REFRESH SENSOR DATA

The correct alignment of the Urine Sample Carrier before the measurement is crucial for the correct acquisition of microscopic images. If no Urine Sample Carrier is detected, recalibrate the associated sensor, even if the Urine Sample Carrier appears to be positioned correctly.


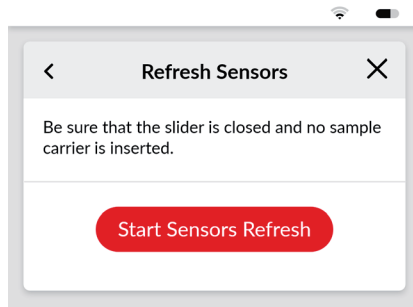

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the menu item "Maintenance".
3. Tap on the menu item "Restore Slide Detection".
4. Tap on "Start Sensor refresh".

FIGURE 35

Start sensor refresh



5. The HumaVision collects the new sensor data.

- The end of the measurement is indicated by “OK”. Confirm the measurement by tapping the confirmation button  .

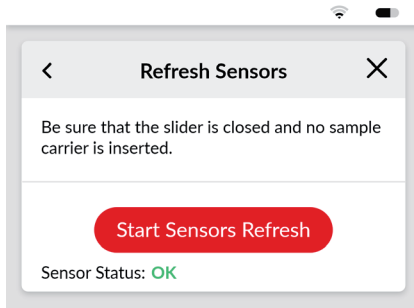


FIGURE 36

Sensor refresh OK

! Note: The instrument must be positioned on a flat surface, without a Urine Sample Carrier but with the sample carrier holder and closed cover.

4.8.3 QUALITY CONTROL

Running a quality control is not mandatory for the routine use of the HumaVision microscopy function. An external quality control can be used for testing purpose or if required by local regulations.

5 SETTING UP THE HUMAVISION

5.1 Settings menu

Click on the settings icon (⚙️) to access the settings menu. The settings can be accessed from any menu. The HumaVision is supplied pre-configured. Hence, configuration of the settings is not necessary, although it may be useful.

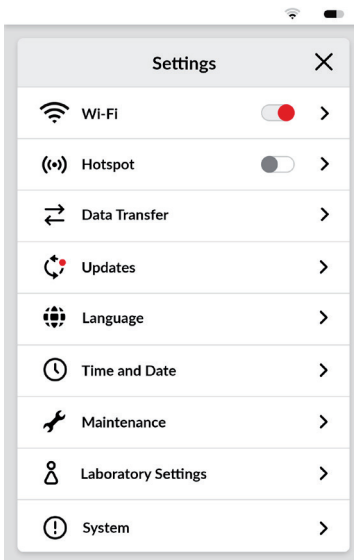


FIGURE 37
Settings screen

	Name	Function
TABLE 5	WLAN button	Shows WLAN settings (see chapter 5.2 Configuration of the WLAN adapter)
	WLAN switch	Enables / disables WLAN (see chapter 5.2 Configuration of the WLAN adapter)
	Hotspot button	Shows hotspot menu (see chapter 5.2 Configuration of the WLAN adapter)
	Hotspot switch	Enables /disables hotspot (see chapter 5.2 Configuration of the WLAN adapter)
	Update button	Shows update menu (see chapter 5.3 Software update)
	Update indicator	Signals an available software update (see chapter 5.3 Software update)
	Maintenance	Sensor status and refresh (see chapter 4.8 Quality assurance)
	Language	Shows language settings menu (see chapter 5.4 Language settings)
	Laboratory Settings	Adapt the PDF print out, add laboratory name etc.
	Time/ date	Show the Time / date settings menu
	System	Shows the instrument's information (see chapter 5.6 Displaying system information)

5.2 Configuration of the WLAN adapter

5.2.1 DESCRIPTION OF OPERATING MODES

! **Note:** Setting up the WLAN adapter is not necessarily for the basic, standalone use of the HumaVision. However, full configuration of the WLAN adapter is recommended to benefit from software updates on the HumaVision.

The HumaVision has a built-in WLAN adapter. It supports various modes, which offer different functions. In the configuration, the following modes are available:

WLAN mode: Connect HumaVision to an existing wireless network (WLAN) to establish connections, e.g., PC, laptop or a server. If the WLAN has internet access, extended functions (e. g., software updates) are available (see chapter 5.3 **Software update**).

Hotspot mode: Set up a device-specific wireless network (WLAN) on your HumaVision, which allows other devices, e. g. laptops, to connect to it (see chapter 5.2.3 **Hotspot mode**).

Offline mode: In this mode, the WLAN adapter of HumaVision is switched off. WLAN and hotspot are disabled. Wireless communication with other PCs or update servers is not possible (see chapter 5.2.4 **Offline mode**).





! Note: If the HumaVision connects to a WLAN that is connected to the internet, it can receive and install software updates directly.

! Note: Obstacles such as walls, glass windows, machines and liquid containers located between the HumaVision and the WLAN access point (e. g., router) or a network device in hotspot mode may affect the quality of the WLAN connection, reduce the data transfer rate and result in dropped connections.

- !** **Note: Connectivity problems may also occur:**
- If metallic stickers are attached near the HumaVision's antenna.
 - If a metal cover is attached to the HumaVision.
 - If the HumaVision's antenna is covered by hands or other objects during mobile data transmission.

5.2.2 WLAN MODE


To connect the HumaVision to an existing WLAN:

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the switch to the right of [Wi-Fi]. When the switch turns green, WLAN mode is enabled (this disables hotspot mode). A grayed-out WLAN icon  appears in the menu bar.
3. Tap on [Wi-Fi] to open the WLAN settings.
4. The instrument now searches for available WLAN networks and, when the search is complete, the names (SSID) of the available networks are listed.
5. Tap on the name of the WLAN to which to connect the instrument to.
6. If necessary, enter the password for accessing the WLAN network and confirm the entry by tapping the confirmation button .
7. The instrument has successfully connected to the WLAN if the WLAN icon  on the menu bar shows the signal strength.

! Note: Not all WLAN networks allow new devices to be added without prior registration of the device by the network administrator (e. g., networks with MAC address or port filtering). To establish connections to the client software, the HumaVision requires the use of port 8080. To obtain online software updates for the instrument (recommended), the HumaVision requires internet access to port 443 (https).

5.2.3 HOTSPOT MODE

The following chapter describes how to create a WLAN network (hotspot) using HumaVision. Add other WLAN-enabled devices to this network to allow communication with the instrument.


1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap the switch to the right of [Hotspot]. When the switch turns green, hotspot mode is enabled (this disables WLAN mode).
3. Tap on the word [Hotspot].
4. The display shows the data with which other WLAN-enabled devices, e. g., PC or laptop, can access the WLAN hotspot generated by the HumaVision:
 - Network name: "humavision-" + the last 6 digits of the serial number
 - Default password: humavision
 - IP address: 192.168.200.1

5. Hotspot mode has been successfully enabled if the hotspot icon (📶) appears on the menu bar.
6. Access the newly created WLAN hotspot with other WLAN-enabled devices (PC, laptop) using the provided data.

! Note: The necessary steps for connecting a PC or laptop to the HumaVision's WLAN hotspot may be found in the manual for the product in question (keyword "Connecting to WLAN networks").

5.2.4 OFFLINE MODE

The following chapter describes how to disable the HumaVision WLAN adapter if the WLAN or hotspot function has been enabled.

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the switch to the right of [WLAN] so that it is grayed out. When the switch is grayed out, WLAN mode is disabled.
3. Tap on the switch to the right of [Hotspot] so that it is grayed out. When the switch is grayed out, Hotspot mode is disabled.
4. Both WLAN and Hotspot mode are now disabled. As a result, the instrument is in Offline mode.

5.3 Software update

Software updates can be provided for the HumaVision by HUMAN. They are available on the HUMAN homepage in the login area. As part of the updates:

- security features are updated.
- known software bugs are removed.
- performance improvements are implemented.
- operating concepts are optimized.

Software update checks for HumaVision are performed automatically if Wi-Fi is configured and internet connection is available (see chapter 5.2.2 **WLAN mode**). Furthermore, the user can manually perform an update check, as described below.


Updates always require the consent of the user.



! Note: In order to receive software updates for the instrument, it is necessary for the HumaVision to be connected to a **WLAN** and be authorized to access the internet. If in doubt, consult a network administrator in order to permit internet access for the HumaVision.

! Note: For the installation of the update, the battery level must be at least 50 %. Otherwise, the installation will be aborted for safety reasons.

Update:

Updates are only possible if the instrument is configured in WLAN mode and integrated within a WLAN with internet access (see chapter 5.2.2 **WLAN mode**):

1. Open the settings menu of the HumaVision by tapping the settings icon  once.
2. Tap on the menu item [Updates].
3. Tap on the [Check for update] button if it is present. If it is not present, skip this step.
4. Tap on [Install update].
5. The updates are now transmitted to the HumaVision. This process may take several minutes.
6. The updates are installed. This process may take several minutes.
7. The installation is complete once the instrument has automatically restarted.

! **Note:** If the HumaVision is connected to a WLAN with **•** internet access, the instrument regularly and automatically checks for software updates. The HumaVision notifies about an available update with a red dot on the settings icon  and the update icon .


! **Note:** If a new software update is available, a message **•** window appears within the update menu in the bottom right-hand edge of the screen with the appropriate text.

5.4 Language settings

The text on the HumaVision's graphical user interface can be displayed in various languages. The following languages are installed and can be selected when the instrument is delivered:

- English (default setting)
- German
- French
- Spanish
- Italian
- Russian


It is possible to set a different display language as follows:

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the menu item [Language].
3. Select the desired display language by tapping on the relevant name. The new setting is applied, and the display changes straightaway.

5.5 Time and date settings

It is important that HumaVision has the correct time and date to create a correct time and date stamp for every measurement. If HumaVision has access to Wi-Fi, the time and date is set automatically using details provided by the network to adjust the date and time. Thus, the instrument can automatically change the settings to match the time and date of any country without a need of any further manual intervention. If not, the date and time have to be set manually including a time zone.

Time and date on the HumaVision can be changed as follows:

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the menu item [Time/ date].
3. Automatic time and date settings are allowed by default.

If not provided or denied:


- select a respective time zone.
- set a local time and date.

4. Select the time format.

! **Note: Set the correct time and date before using the instrument.**

5.6 Displaying system information

System information for the HumaVision can be displayed as follows:

1. Open the settings menu of the HumaVision by tapping the settings icon .
2. Tap on the menu item [System].
3. The instrument information is displayed.

The instrument information includes the following details:

- The instrument model name,
- the serial number of the instrument,
- the currently installed software version,
- the MAC address of the WLAN adapter,
- the hostname.

5.7 Connectivity for PDF export

Make sure the HumaVision is connected to the same Wi-Fi as the PC the PDF file should be exported to. Navigate to “Settings” and click on “Data Transfer”, to set up a connection.

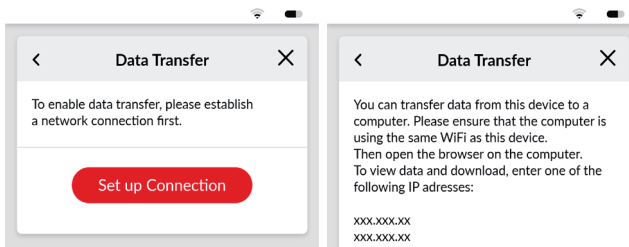


FIGURE 38
Data transfer

5.8 Customize the printout or PDF file

The printouts or PDF files can be customized by following the steps below:


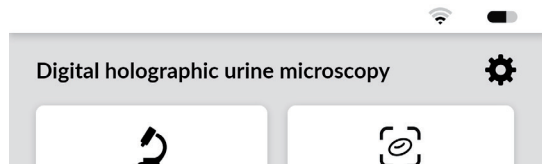
1. Open the settings menu of the HumaVision by tapping the settings icon .

FIGURE 39

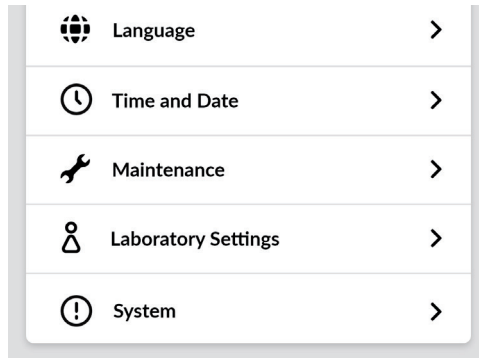
Top bar of main menu



2. Scroll down and select “Laboratory Settings”.

FIGURE 40

Settings screen



The new screen “Laboratory Settings” opens, where the printout can be customized.

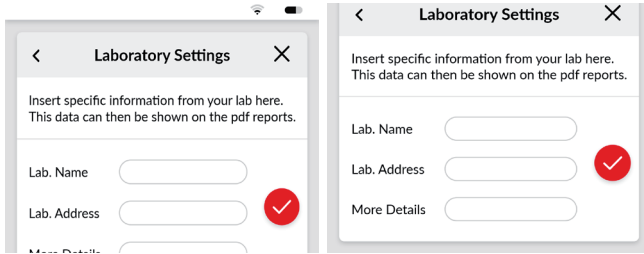


FIGURE 41
Laboratory settings

The printout or PDF file can be customized by adding the name of the laboratory name, the address, and for further information in the header of the PDF, the field “More Details” can be used.

Laboratory xyz, Street, Town, More Details

Microscopy Image

Metadata

Sample ID:	123456790
Measurement ID:	12-12
Urine Colour:	Colourless
Urine Clarity:	Clear
Dilution:	1:5
Device Serial No:	123
Software Version:	1.0
Algorithm Version:	1.2

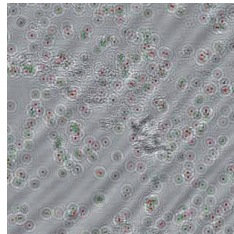


FIGURE 42
Printout or PDF file example

5.9 Provide support data

For support purposes, the function “Provide Support Data” can be used to share measurement data with HUMAN's Service.

This function is available in the menu “Settings > System > Provide Support Data”.

Measurement data can be uploaded manually by clicking the “Upload now” button.

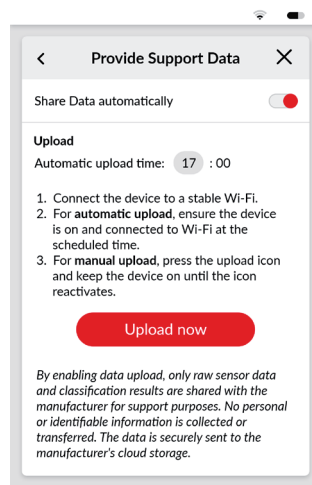
Additionally, an automatic upload can be activated via the button “Share Data automatically”. If this button is activated, measurement data is uploaded daily at the time specified in the field “Automatic upload time”. During this time, the instrument must be switched on and connected to the Wi-Fi.

By default, this function is deactivated, so no data can be shared without permission of the user.

By enabling the data upload, only raw sensor data and classification results are shared with the manufacturer for support purposes. No personal or identifiable information is collected or transferred. The data is securely sent to the manufacturer's cloud storage.

FIGURE 43

Provide support data



6 OPERATING AND MAINTENANCE INSTRUCTIONS

6.1 Prohibitions on use

Do not use the instrument:

- in potentially explosive environments,
- with hazardous substances (corrosive, flammable),
- with hot liquids ($> 60\text{ }^{\circ}\text{C}$).

The technical parameters are specified in chapter 7 **Technical specifications**.

6.2 Service life

The HumaVision is suitable for 24/7 use. Portable use is limited by the battery life. The 24/7 operating mode requires a connected external power supply. If the battery is low (20 % remaining capacity), the HumaVision indicates this graphically on the display and the battery icon on the menu bar turns red. If these indications light up, connect the instrument to the power supply unit and charge the battery. If the instrument is not charged, it automatically shuts down if the battery capacity reaches 5 %.

The instrument's service life is determined to a large extent by the battery life. Under ideal conditions with the instrument being used as intended, 300-500 charging cycles would be standard for the built-in battery. Assuming a service life of 5 years, this corresponds to one charge per week.

! **Note:** The instrument may only be charged and operated using the supplied power supply unit described in the specifications (see chapter 7 Technical specifications). If the power supply unit fails, a replacement power supply unit should be requested from the local distributor.

6.3 Usage location

The HumaVision is designed for indoor use in accordance with the conditions specified in chapter 7.1 **HumaVision specifications**. The instrument can be operated outdoors if the conditions specified in chapter 7.1 **HumaVision specifications** are met. During measurement, keep the measuring environment constant to ensure reliable results.

6.4 Cleaning

Contamination must be removed in accordance with chapters 6.4.1 **External cleaning** and 6.4.2 **Cleaning the sensor and measuring chamber**. Cleaning must be carried out in a dry and dust-free condition.

**WARNING****Biohazard**

To prevent accidental contamination of the measuring chamber, the cover must be closed when instrument is not in use.

Contact with the urine samples may result in infection. Hence, the components of the instrument associated with the urine samples are potentially biohazardous. Follow Good Laboratory Practices when working with urine samples. If the urine sample comes into contact with your skin, wash it off immediately with soap and water and apply disinfectant. If necessary, consult a physician.

**WARNING****Electrical hazard**

Before cleaning, disconnect the HumaVision from the main power supply. The instrument must always be switched off during cleaning.

6.4.1 EXTERNAL CLEANING

If the urine sample is spilled on the instrument, wipe it off immediately and apply disinfectant.

The following cleaning supplies are recommended:

- A soft microfibre cloth for the display and housing
- 30 % isopropanol alcohol. Do not use aggressive cleaning agents, such as benzene or acetone. These may damage the display coating.
- If alcohol is used as a cleaning agent, do not apply it directly to the HumaVision. Moisten a cloth with the cleaning agent and then wipe the HumaVision.



CAUTION

Before cleaning the instrument with water or a cleaning agent, squeeze the cloth to remove excess liquid. Prevent liquid from entering the instrument to avoid damaging internal components.



WARNING



Biohazard

Sample residues on the HumaVision may lead to contamination of the user. Wear a fluid resistant lab coat and approved lab gloves.

6.4.2 CLEANING THE SENSOR AND MEASURING CHAMBER

Make sure the cover is closed all the time when no measurement is taking place. Otherwise, dust particles are can get inside the measuring chamber and damage the sensor. Dust particles are too small to be seen by the eye. Thus, cleaning the sensor must be done only with Cleaning Sticks HumaVision, which are for single use only. Otherwise, the sensor can get damaged by scratches.

The measuring chamber should be cleaned weekly in order to maintain the instrument's measuring performance.

Only use the Cleaning Sticks HumaVision (REF 17662) to clean the HumaVision sensor. The use of other sticks is not recommended, and any potential harm caused thereby is not the responsibility of HUMAN.



FIGURE 44
Cleaning Sticks
HumaVision

Besides the mandatory Cleaning Sticks HumaVision, the following cleaning supplies are recommended:

- A soft, clean, lint-free microfibre cloth
- 99 % isopropanol alcohol. Do not use aggressive cleaning agents, such as benzene or acetone, as these may damage the HumaVision.
- If alcohol is used as a cleaning agent, do not insert it directly into the measuring chamber.

! Note: The Cleaning Sticks are for single use only.
• HUMAN is not responsible for damage to the optical components of the instrument caused by contamination or carry-over contamination from reusing Cleaning Sticks.

! Note: Do not point the spray nozzle of a cleaner directly at the HumaVision's light source. Do not use excessive force to clean the sensor avoiding damage to the sensor.

! Note: Do not use compressed air on the measuring chamber, as this may cause particles of dirt to settle on the internal measuring equipment. In this case, a service technician needs to open and clean the instrument.

Procedure in the event of contamination with dry particles (dust etc.):

1. First remove the sample carrier holder and clean it with a soft microfibre cloth.

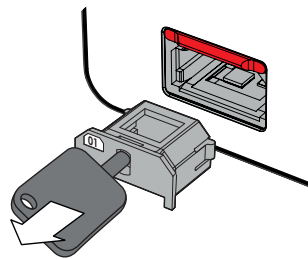
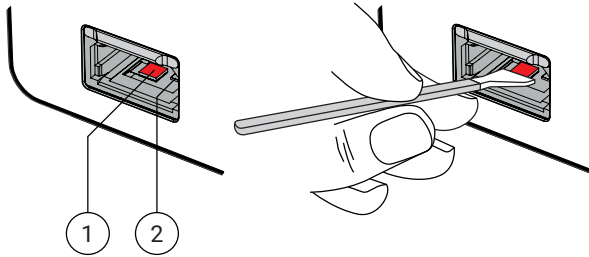


FIGURE 45

Removing the sample carrier holder with the key

2. Turn over the instrument so that the measuring chamber's opening faces downward. Tap gently on the back of the HumaVision so that any dust or loose particles fall out.
3. Use the Cleaning Sticks HumaVision to clean the sensor surface first, then clean the LED.

**FIGURE 46**

Cleaning the sensor surface and the LED

Optical components

- 1 Sensor
- 2 LED

Procedure in the event of heavier contamination (dried fluids etc.):

1. First remove the sample carrier holder and clean it with a soft microfibre cloth moistened with 99 % isopropanol.
2. Turn over the instrument so that the measuring chamber's opening faces downward. Tap gently on the back of the instrument so that any dust or loose particles fall out.
3. Clean the measuring chamber with a soft microfibre cloth moistened with 99 % isopropanol.
4. Clean the sensor surface and the LED with the Cleaning Sticks HumaVision moistened with 99 % isopropanol without exerting excessive pressure.

**WARNING****Biohazard**

Sample residues in the measuring chamber may lead to contamination of the user. Wear a fluid-resistant lab coat and approved lab gloves.

6.5 Transportation/ storage

Store and transport the instrument in the storage box following the conditions in chapter 7.1 **HumaVision specifications**.

Before transportation or storage, clean the instrument in accordance with the cleaning instructions (chapter 6.4 **Cleaning**).

6.6 Decommission

If the HumaVision is not used for a period of > 3 months, store the instrument in the storage box to minimize damage and contamination.

Before the HumaVision is placed out of service, clean it in accordance with chapter 6.4 **Cleaning**.

Place the battery in the optimum charge state for storage, see chapter 1.4.2 **Lithium polymer battery**.

During storage, the storage conditions specified in chapter 7.1 **HumaVision specifications** must be adhered to. The person responsible for storing the HumaVision must have the necessary qualifications for this activity.

6.7 Disposal

This HumaVision and its components contain electronic parts.

EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) specifies that used instruments should not be disposed of as general household waste, laboratory waste or hospital waste. Used instruments must be collected separately, to increase the recycling rate and to reduce the impact on human health and on nature.



The instrument is equipped with a lithium polymer battery. Batteries require special care in handling and disposal (see chapter **1.4 General safety warnings**). Improper disposal may have adverse effects on human health and may harm the environment.

At the end of its product life cycle, dispose of the instrument as electronic waste. Disposal via municipal collection points is not permitted.

! Note: Follow the safety instructions in chapter 1.4 General safety warnings when handling the HumaVision.

The Urine Sample Carrier used for measuring purposes must be disposed of after use in accordance with the customer's own laboratory regulations. If the Urine Sample Carriers have been mixed with human samples, special care is required when handling them.

These samples may be contaminated with pathogenic germs or viruses and must be handled as potentially hazardous.



WARNING



Biohazard

Always wear gloves when working with Urine Sample Carrier to avoid any potential hazards, e. g., contamination with infectious material.

7 TECHNICAL SPECIFICATIONS

7.1 HumaVision specifications

Power supply

TABLE 6

Mains voltage (for charger)	100-240 VAC
Mains frequency (for charger)	50/ 60 Hz
Input current (for charger)	0.35 A
Operating voltage HumaVision	5 VDC
Max. current consumption	1.5 ADC
Max. power:	7.5 W
Battery life (continuous measurement operation):	1.7 h
Battery life (standby, display off):	5.5 h
Battery type	Lithium polymer 3.7 V, 1500 mAh
Charging port	USB-Port Type C

Display

Size	3.5" with 320x240 px (landscape)
Touch screen	Capacitive

WLAN

Frequency range	2400-24835 GHz (IEEE 802.11 b/g/n)
Radio channels	13 at IEEE 802.11 b/g/n (2.4 GHz)
Transfer rate	Realistic transfer rate: 35 Mbps IEEE 802.11 b up to 11 Mbps IEEE 802.11 g up to 54 Mbps IEEE 802.11 n up to 300/450 Mbps
Security	WPA/WPA2

Operating system	Linux
Memory	300 measurements
Nominal operating range	
Ambient temperature	18 to 25 °C
Charging temperature	15 to 30 °C
Relative humidity	< 80 %, without condensation at 31 °C

Transport/ storage conditions

Ambient temperature	- 25 to + 50 °C (optimum: 20 °C)
Relative	Max. 95 % at 25 °C (optimum: 40-60 %)
Duration of transport/ storage	Max. 6 months/ max. 1 year

Safety conditions

Degree of pollution	2
Protection class in accordance with DIN VDE 106 T1	SK II
Degree of protection according to IEC 60529	IP20 IP2X \triangleq Protection against ingress of solid foreign bodies $\varnothing \geq 12.5$ mm IPX0 \triangleq No protection against ingress of water

Dimensions ($L_x \times W_z \times H_y$)

HumaVision	128 mm x 94 mm x 33 mm
------------	------------------------

Weight

HumaVision	240 g
------------	-------

Microscope assembly

Resolution	Particle size: 3 μ m-100 μ m
------------	--------------------------------------

7.2 Accessories

Name	REF number	Description
USB power supply unit, external, type 31507W	17660/105	Accessory HumaVision
USB connection cable [type A to type C]; 1.8 m	17660/106	Length: 1.8 m
Urine Sample Carrier HumaVision	17661	4x25 sample carriers in box (box of 4x25 is the packing unit)
Cleaning Sticks HumaVision	17662	Set of 8x12 is the packing unit, see chapter 6.4.2 Cleaning the sensor and measuring chamber
Sample carrier holder	17660/101	Sample carrier holder (inserted in the instrument; to be removed only during cleaning)
Sample carrier holder key	17660/100	Tool for removing the sample carrier holder (for cleaning)

TABLE 7

HUMAN

Gesellschaft für Biochemica und Diagnostica mbH

Max-Planck-Ring 21 • 65205 Wiesbaden • Germany

Tel.: +49 6122/9988 0 • Fax: +49 6122/9988 100

eMail: human@human.de • www.human.de

The logo graphic consists of a stylized red and white shape resembling a folded ribbon or a stylized 'H' that tapers to the right.

Human

Diagnostics Worldwide