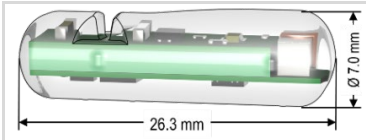
HemoPill® ACUTE

ovesco

Instructions for use | **U.S.A.**

Ref. № **500.01**



Capsule dimensions:
Length 26.3 mm
Maximum diameter Ø 7.0 mm

PRODUCT DESCRIPTION

The HemoPill acute is an active diagnostic medical device. The capsule is battery operated and features a housing with a measuring gap containing an optical sensor. The signals of the HemoPill acute sensor correlate with the presence of blood in the measuring gap of the capsule and are transmitted wirelessly to the HemoPill Receiver.

The HemoPill acute is able to detect liquid blood (or hematin) in quantities of ≥ 20 ml with a sensitivity and specificity of > 80%*.

The HemoPill acute is designed only for use with the HemoPill Receiver (ref. no. 500.20, Ovesco Endoscopy AG).

**Data is based on scientific analysis confirmed by a clinical study (DING study).*

INDICATION

The HemoPill acute is used for diagnosis in patients with suspected acute bleeding in the esophagus, stomach, and small intestine. The HemoPill acute is intended for use in adults and young patients aged 14 years and above. There is no clinical data concerning use on patients aged between 14 and 18. The HemoPill acute is administered by swallowing.

CONTRAINDICATION

Use of the HemoPill acute is contraindicated in the following conditions:

- known gastrointestinal obstruction, stricture, fistula, or diverticula
- dysphagia or other swallowing disorders
- during pregnancy
- impaired consciousness that prevents autonomous swallowing of the capsule
- in patients with cardiac pacemakers and other implanted electromedical devices

COMPLICATIONS

The following complications are possible when the HemoPill acute system is used as intended:

- aspiration of the capsule on ingestion
- delayed excretion, or failure to excrete the capsule (capsule retention)
- obstruction of the digestive tract
- injury to tissue structures during the passage of the HemoPill acute through the digestive tract. In particular, this may involve:
  - injury to the mucosa
  - bleeding, e. g. variceal bleeding
  - perforations

GENERAL INFORMATION

Using these instructions for use
Carefully read these instructions for use and the instructions for the HemoPill Receiver before using the HemoPill acute. The user should have fully understood how the product works and how it should be handled.

The user must ensure that the HemoPill acute system is used and the measured values are interpreted in accordance with the instructions for use.

Using this product
The product must be used only for its intended purpose. Even if the product is used as intended, side effects may occur. For this reason, Ovesco products should only be used by persons who are qualified and trained to use the specific products for their intended purpose. The HemoPill acute can be used by doctors, nursing staff or medical staff with equivalent training.

BEFORE USE

1. Switching on the HemoPill Receiver

Switch on the HemoPill Receiver and select the "Connect" menu (see instructions for use for the HemoPill Receiver).

2. Activating the HemoPill acute

The HemoPill acute must be activated before it is removed from the blister packaging. The capsule is activated by light in the activation area of the capsule (**1**). Use the LED light source integrated in the HemoPill Receiver (**2**).

Switch on the LED via the display on the HemoPill Receiver and press the "LED" button in the "Connect" menu. The LED will light up for approx. 5 seconds after you have pressed the button.

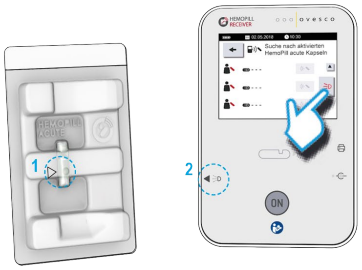


Figure 1

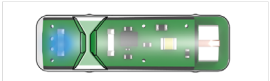
Place the blister packaging against the left side of the HemoPill Receiver and align the grey triangle markings on the blister and the HemoPill Receiver to each other.

Hold the blister immediately next to the LED of the Receiver (fig. 2). If necessary, move the blister slightly around the LED of the Receiver.

Figure 2

When the capsule is activated, the light source of the capsule flashes at regular intervals. Note the color of the flashing signal (fig. 3):

Flashing blue:
HemoPill acute is ready for use.



Flashing red:
HemoPill acute is defective and must not be used.

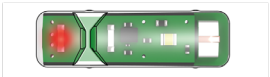


Figure 3

3. Establishing a data connection

Comparing the capsule ID
When establishing a data connection, it is important to ensure that the capsule ID shown on the HemoPill Receiver matches the capsule ID on the blister packaging. Connecting to an incorrect HemoPill acute can lead to false negative results.

The capsule ID is indicated directly on the blister packaging.

The separately enclosed patient labels (four stickers) serve the documentation in the patient file.

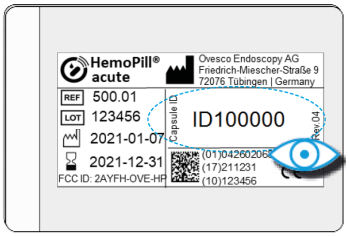


Figure 4

Press the "Connect" button in the main menu of the HemoPill Receiver (see instructions for use for the HemoPill Receiver).

Select the capsule ID of the HemoPill acute to which you want to establish a connection (**1**).

For the connection, press the "Connect" button next to the corresponding capsule ID (**2**).

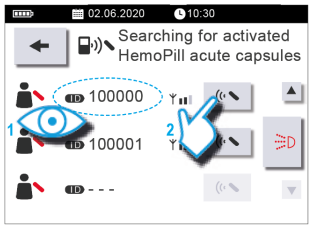


Figure 5

The measurement diagram for the selected capsule is now shown on the display of the HemoPill Receiver.

USE

1. Handing the HemoPill acute to the patient

Handing over the HemoPill acute
When handing the capsule to the patient, ensure that it is activated in the blister and is not contaminated.

Only remove the paper cover on the rear side of the blister. This can easily be pulled off in one direction.

After opening, hand the blister to the patient for the removal of the capsule (fig. 6).

The blister packaging is designed to enable the patient to remove the capsule with two fingers.

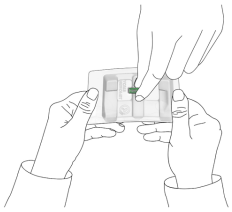


Figure 6

Ensure that the patient holds the capsule in the center, on the sides, and does not obscure the area of the flashing measuring gap!

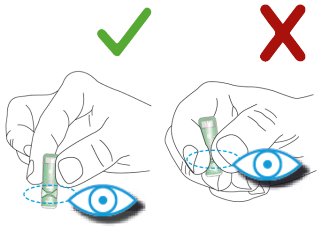


Figure 7

Checking the data reception after handing to the patient
After handing the capsule to the patient, check that there is still a data connection between the HemoPill acute and HemoPill Receiver. To do this, ensure that the blue LED on the HemoPill Receiver has lit up at least twice before the patient swallows the capsule.

2. Ingesting the capsule

Do not bite on the capsule
Instruct the patient that they must not bite on the capsule before swallowing.

Ingest the HemoPill acute with water
The HemoPill acute must be taken with at least 100 ml water. The water aids swallowing and promotes the suspension of blood.

3. Receiving and reading measured values

Interruption of the data connection
During the measurement, the data connection may be spontaneously lost for a variety of reasons. Ensure that the HemoPill Receiver is positioned as close to the patient as possible during the measurement, and never further than 50 cm away from the patient. Also ensure that there are no sources of interference (e.g. wireless headphones, wireless keyboards, etc.) nearby.

After the patient has taken the HemoPill acute, the measured values (HI values) are shown on the display of the HemoPill Receiver. The HemoPill acute continuously sends measured values to the HemoPill Receiver several times per minute. The duration of the measurement is approx. 9 hours from activation of the HemoPill acute.

The values measured by the capsule are displayed numerically and as a curve diagram on the display of the HemoPill Receiver.

The numerical display shows the maximum HI value (^{MAX}HI) and the last measured value (^{LAST}HI) (**1** and **2**). The respective measuring time is located below.

^{LAST}HI is updated several times per minute with each measured value received.

^{MAX}HI updates every minute during the first hour, after the first hour until the 9th hour about every 8 minutes. The ^{MAX}HI value is also plotted as a curve over time.

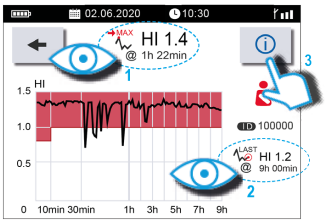


Figure 8

For information on interpreting the HI values, press the „Info“ button (**3**).

Monitor the data connection
Monitor that the data connection is present during measurements by comparing the time of the last measured value against the current time on the display of the HemoPill Receiver.

Display lock
The display switches off automatically 5 minutes after swallowing the capsule and the touch function is deactivated (display lock). To turn the display back on, press the power button on the front of the unit. The display is now fully bright again and the display lock is released.

During measurement recording, the display always switches off after 15 seconds. This process also occurs when the HemoPill Receiver is connected to the power supply.

4. Interpretation of the measured values

We recommend the following procedure for the interpretation of the HI values: First, interpret the maximum HI value within 10 minutes from swallowing the HemoPill acute. (See Table 1).

Then interpret, independently of this, the maximum HI value in the further course of the measurement (≥ 10 minutes after swallowing, see table 2).

The duration of the measurement is approx. 9 hours.

Interpretation recommendations for the detection of blood using the HemoPill acute system are provided in the following table:

HI	Within 10 minutes after swallowing
< 0.8	**Negative** Liquid blood (or hematin) was not detected. NOTE: Blood may still be present but may be highly diluted or exist in unsuspended, adherent coagula.
≥ 0.8	**Positive** Liquid blood (or hematin) was detected.

Table 1

HI	> 10 minutes after swallowing
< 1.0	**Negative** Liquid blood (or hematin) was not detected. NOTE: Blood may still be present but may be highly diluted or exist in unsuspended, adherent coagula.
≥ 1.0	**Positive** Liquid blood (or hematin) was detected.

Table 2

The HemoPill acute is able to detect both undiluted blood and diluted blood. Under laboratory conditions, a solution of 6.25% blood in water leads to a HI value of at least 0.8.

AFTER USE

1. Deactivating the data connection

To end the measurement, deactivate the data connection in the HemoPill Receiver menu. This ends the measurement recording. The data connection can be re-established at any time within the measurement period of the HemoPill acute (approx. 9 hours).

2. Checking the excretion of the HemoPill acute

The HemoPill is excreted through being passed naturally by the patient. To check that this has occurred, the transmission function of the capsule is active for at least 21 days. For more information, see the instructions for use of the HemoPill Receiver.

If the HemoPill acute is identified in the patient at a time when the capsule should have already been excreted, abdominal X-ray and subsequent extraction could be taken into consideration.

WARNINGS AND PRECAUTIONARY MEASURES

Sterile single-use product
The HemoPill acute is a sterile single-use product. The materials used are not suitable for disinfection or sterilization. The components of the product are designed for single use and do not withstand multiple use. Reprocessing and reuse of disposable instruments may harm the patient (inadequate function, insufficient sterility, contamination, corrosion, or other impairment).

Check for damage to packaging / expiration date
Check for damage to the packaging and note the use-by date. If the packaging has been damaged or the use-by date has expired, the sterility of the product cannot be guaranteed.

Damage to the HemoPill acute
After removing the product from its packaging, the components must be inspected for damage. Damaged parts may lead to incorrect operation or may cause injury to the patient and user. Separate out the damaged product immediately. Attempts at repairing the product are not permitted.

Use in the vicinity of active HF surgical devices
Do not use in the vicinity of active HF surgery devices. Active HF surgical equipment must not be used while taking measurements using the HemoPill acute capsule.

Maximum temperature in the event of a fault
The maximum temperature in the event of a fault is 43°C for a duration of < 5 minutes. No effects on the patient's condition are expected.

Compatibility note
Make sure that the software versions of the HemoPill Receiver and HemoPill acute are compatible (see HemoPill Receiver instructions for use, chapter 22).

Use in the vicinity of electrical devices
Use of the HemoPill Receiver or the HemoPill acute in the immediate vicinity of other electrical devices should be avoided as this may lead to malfunctioning.

Use of the accessories provided
The use of accessories, transducers (mains adapters) and cables other than those specified or provided by the manufacturer of this device may result in increased electromagnetic interference transmission or reduced electromagnetic immunity of the devices and lead to malfunctioning.

Use in the vicinity of HF communication devices
Portable HF communication devices (e. g. mobile phones, devices with radio function), including their accessories such as aerial leads and external aerials, should be at least 30 cm away from the components indicated by the manufacturer and the cables of the HemoPill acute or the HemoPill Receiver. Failure to comply may lead to a drop in product performance.

FCC Warning
This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation (cf. *CFR 47*, part 15, rule 19).

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

– Reorient or relocate the receiving antenna.
– Increase the separation between the equipment and receiver.
– Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
– Consult the dealer or an experienced radio/TV technician for help.

(cf. *CFR* 47, part 15, rule 105).

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows:
Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations."

Changes or Modifications to the HemoPill acute:
Changes or modifications made to this device not expressly approved by Ovesco Endoscopy AG may void the FCC authorization to operate this device.

OPERATING CONDITIONS

- Only use the HemoPill acute at temperatures between +20°C and +40°C (operating temperature).

TRANSPORT AND STORAGE CONDITIONS

- Transport and store the product in sterile packaging dry and dust-free.
- Details of the transport conditions are provided in the product labelling.
- Do not place the product in direct or indirect sunlight or other UV radiation.
- Store the product at room temperature in a dust-free, dry environment.
- Do not store near chemicals, disinfectants, or radioactive radiation.
- Do not place any objects on the product or its packaging.
- Incorrectly stored products will not be taken into consideration in the event of complaints.

Damage to the packaging / transport/storage
The packaging must not become damaged, wet, or contaminated because the sterility of the product can then no longer be guaranteed. Improper transport and storage conditions may lead to a malfunction of the system or a risk of infection or tissue irritation for the patient.

MRI SAFETY INFORMATION

MR Conditional

Pre-clinical testing and assessments have shown that the HemoPill acute capsule is safe for use with MR under certain conditions. Patients can safely undergo an MRT examination after swallowing the capsule under the following conditions:

– Static magnetic field is 1.5 Tesla or 3 Tesla
– Spatial gradient of the magnetic field is no more than 450 Gauss/cm (4.5 T/m)
– Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (per pulse sequence) in the First Level Controlled Operating Mode for the MRI device.

MRI-related heating
Under the aforementioned scan conditions and during an examination lasting for 15 consecutive minutes (i.e. per pulse sequence), the HemoPill acute capsule is warmed by a maximum of 1.6°C.

Image artefacts
Under certain circumstances, the MRT image quality may be affected if the investigation takes place within the application area or is directly adjacent to it. Pre-clinical trials have shown that image artefacts caused by the HemoPill acute capsule may spread up to approx. 40 mm from the capsule, if the imaging is performed using a gradient echo pulse sequence and a 1.5 Tesla MRI device, and up to approx. 50 mm using a gradient echo pulse sequence and a 3 Tesla MRI device.

Device function after MRI examination
In non-clinical testing involving the use of various standard pulse sequences for clinical MRI examinations at 1.5-Tesla/64-MHz and 3-T/128-MHz, the functionality of the HemoPill acute capsule was not impaired or damaged.

Rx only!
Caution: Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

HemoPill is patent protected in the USA:
US 7828730, and patent pending: 17/160,937

Distributed in the USA by: Ovesco Endoscopy USA, Inc.
120 Quade Drive | Cary, North Carolina 27513
Phone: +1 919 651 9449 | Fax: +1 408 608 2077
customerservice@ovesco-usa.com

EXPLANATION OF THE SYMBOLS ON THE PACKAGING

FCC ID: 2AYFH-OVE-HP

CE 0124 CE mark and identification number of the notified body

Follow the instructions for use

LOT Batch number

Capsule ID # Capsule ID

REF Reference number or ordering number

During operation of the device, electrical energy is applied, which generates electromagnetic radiation.

Manufacturer

YYYY-MM-DD Date of manufacture: year-month-day

YYYY-MM-DD Use by: year-month-day

STERILE EO EO (ethylene oxide) sterilized

Rx only (U.S.A.) Attention! Only to be used by trained personnel

Not suitable for re-use

Do not re-sterilize

Do not use if packaging is damaged

Protect against heat (solar radiation)

Temperature limitation

1 Number of items per package

Applied part type BF

MR MR Conditional

not made with natural rubber latex Latex-free

TECHNICAL DATA

Battery type	Silver oxide	Dimensions	26.3 mm x 7.0 mm	Weight	Approx. 2 g
Wireless specification					
Operating frequency range	433.05 MHz to 434.79 MHz	Send frequency	434.42 MHz	Send bandwidth	100 kHz
Send rate	HP acute software version ≥ 2.03.00-01: 0.083 Hz	Modulation	GFSK	ERP	-24 dBm
Environmental conditions for operation, transport and storage					
	Operation	Storage		Transport	
Temperature	+20°C to +40°C	+10°C to +30°C		-10°C to +50°C	
Relative humidity	20% to 90% RH; non-condensing	20% to 85% RH; non-condensing		20% to 90% RH; non-condensing	
Air pressure	785 to 1,060 hPa	700 to 1,060 hPa		700 to 1,060 hPa	
Max. operating height	≤ 2000 m	-		-	

EMC INFORMATION

Ensure that no electronic devices that may be affected by electromagnetic fields are located in the vicinity of the HemoPill acute. Any electromagnetic interference can lead to malfunctions and/or failure of the corresponding device and may therefore endanger users or patients.

Medical electrical devices are subject to specific precautionary measures relating to EMC and must be installed and commissioned in accordance with the EMC instructions contained in the accompanying documentation.

Guidelines and manufacturer's declaration: Electromagnetic immunity	
The HemoPill acute is intended for use in an electromagnetic environment as specified below. The user must ensure that the device is operated in such an environment.	
Measurement of emitted interference	Conformity
HF emissions acc. to CISPR11	Group 1
HF emissions acc. to CISPR11	Class B

Guidelines and manufacturer declaration: Electromagnetic resistance		
The HemoPill acute is intended for use in an electromagnetic environment as specified below. The user must ensure that the device is operated in such an environment.		
Immunity test	**IEC 60601-1-2:2014 test level**	**Compliance level**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 2, 4, 8 and 15 kV air discharge	± 2, 4 and 8 kV air discharge
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m	30 A/m
HF radiated disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz [a] 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz

[a] Test specifications for interference resistance of the housing to wireless telecommunication devices

Test frequency (MHz)	Band (MHz)	Use	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine wave	2	0.3	28
710 745 780	704–787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
1,720 1,845 1,970	1,700–1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2,450	2,400–2,570	Bluetooth, WIFI, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5,240 5,500 5,785	5,100–5,800	WIFI 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9