

CompactOne 9

WHOLE BLOOD COAGULATION SYSTEM

USER MANUAL

TABLE OF CONTENTS	
INTENDED USE	3
SUMMARY AND EXPLANATION	3
OPERATING PRINCIBLE	3
TERMS AND DEFINITIONS	4
SPECIFICATIONS	4
SYMBOLS & LABELS	5
TECHNICAL SPECIFICATIONS	5
INSTALLATION	7
PC AND PRINTER CONNECTIONS	8
CHARGING THE BATTER	8
BATTERY PRECAUTIONS	9
KEYPAD	10
USER INTERFACE	11
DATE & TIME	11
PID & UID IDENTIFICATION	12
TEMPERATURE DISPLAY	14
NS DISPLAY	15
ONLINE TEST DISPLAY	16
OPERATION	16
QUALITY CONTROL	18
ACCESSING THE QC PROCEDURE	19
PRECAUTIONS	19
RESULTS	20
TROUBLESHOOTING	22
MAINTENANCE	23
TECHNICAL FEATURES OF PHERIPHERAL UNIT	23

This manual is published by HEMONART Medikal Sistemler Sanayi Ticaret A.Ş. for the use of Hemonart brand CompactOne 9 model device.

Questions or comments regarding the contents of the manual can be directed to the address on the back of the manual. Within the scope of the continuous product development program, HEMONART LTD. reserves the right to make changes to this equipment and documentation without prior notice. Image copyright HEMONART Medikal Sistemler Sanayi Ticaret A.Ş. and cannot be reproduced or copied in any way without prior permission.

INTENDED USE

Hemonart CompactOne 9 was design for professional use in clinical settings for the management of hemostasis by quantitative determination of coagulation tests, including whole blood coagulation techniques such as activated clotting time (ACT), Prothrombin Dose Assay (PDA), Heparin Response Time (HRT) and Prothrombin Response Time (PRT). For in vitro diagnostic use only.

SUMMARY AND EXPLANATIONS

Administration of heparin during cardiac surgery and cardiac angioplasty procedures may pose a risk to the patient. Heparin overdose may cause dangerous bleeding, while insufficient heparin dose may lead to thrombosis because of the different heparin sensitivity in patients. Therefore, heparin levels should be monitored. ACT test is the preferred method for monitoring heparin therapy.

ACT is performed by measuring the time taken for clot formation after the blood sample is added to tubes containing activators such as celite[®], silica, kaolin and glass particles that activate coagulation. The coagulation activator used shortens the time required for clot formation. Celite[®] (diatomic soil) is the standard ACT reagent used for high level heparin monitoring due to its excellent activation properties. However, serine protease inhibitors such as aprotinin that can be applied in some patients may prolong the ACT activated with celite[®]. When aprotinin is administered, ACT tubes containing kaolin should be used.

OPERATING PRINCIPLE

Hemonart CompactOne 9 includes a test well in which single-use coagulation test tubes can be placed (Figure 1). Test tubes sold separately contain reagents for a particular test. After the blood sample is added to the test tube, press the START button, shake the test tube and place it in the test well. Here it is rotated automatically at a controlled speed and incubated at 37 ° C \pm 1.0 ° C.

As the fibrin clot starts to form, the magnet in the test tube changes its place. Since the detectors in the test well monitor the magnet position. When a certain displacement occurs in the magnet, the device gives an audible warning indicating that the test has ended and give the result as second.

The coagulation time is displayed on the screen of the device. The operator can choose to print the result (for this the device must be connected to an external printer) or save the result and proceed to a next test.



Figure 1: Hemonart Compaq one 9-Whole blood Coagulation System

Notes : Disposable ready-to-use test tubes must be purchased separately. Test tubes from other manufacturers may be used, but clotting time results may differ significantly. When using test tubes from other manufacturers, laboratory performance must be verified.

The system continuously monitors the contents of the tube while rotating the test tube at a constant speed and keeps the sample tube at 37°C until end of test.

Along with the clot formation, the device gives a "BEEP" sound and the clotting time is displayed on the display panel. The result is also stored in the system database with the exam type as well as the date and time the test was performed. If entered, the PID and OID are also stored with the test result. If desired, it can be printed using an external printer.

TERMS AND DESCRIPTIONS

Acronyms and abbreviations used in this manual and device screen are as follows.

ACT	Activated Clotting Time
NS	Coagulation trend
HCDM	Hemonart Compact Data Manager (Software)
LQC	Liquid Quality Control
EQC	Electronic Quality Control
UID	User Identification Number
PIN	User Personal Identification Number
PID	Patient ID Number
POCC	Point of care Coordinator
QC	Quality Control

SPECIFICATION

- 1. System is suitable for POC use, easy to carry.
- 2. Fresh whole blood can be used with appropriate test tubes.
- 3. 2 ml whole blood from sample is required.
- 4. Successful or incorrect results are automatically tagged with date and time
- 5. Results are reported in seconds and NS
- 6. Results of 2000 tests can be stored when the optional PID, OID and user note is entered.
- 7. Stored results can be reviewed by test type, PID, OID or by date.
- 8. System checks are carried out automatically.
- 9. There is an EQC that controls the operation of the test well and the electronics of the detector.
- 10. The screen is illuminated to be seen in low light.
- 11. The display can show the percentage of remaining battery power numerically or graphically.
- 12. When the battery is low, the user is warned.
- 13. A printer can be connected to the system.
- 14. It has external serial port (RS-232).

SYMBOLS & LABELS

Before using Hemonart CompactOne 9, the contents of this user manual, the labels on the device or its packaging, and the instructions that come with the tubes must be read and understood by the operator. These materials refer to additional symbols described below.

Ĩ	Fragile, Handle with care
2	Expiration Date
LOT	Lot Number
X	Storage temperature ranges
Ti	Consult instruction for use
	RS232 serial port
SN	Serial Number
CE	CE Conformity
IVD	For in vitro diagnostic use
\wedge	Caution, consult accompanying documents
$\sim \sim$	Production date.
	Manufacturer
X	Medical Equipment Pursuant to Article S of Directive 2002/96 / EC, Annex 1A, on Waste of Electronic Equipment - Contact Technical Support
REF	Catalogue Number

TECHNICAL SPECIFICATION

Technical features of Hemonart CompactOne 9 Whole Blood Coagulation System are listed below.

Dimension & Weight	Depth	20cm
	Width	14cm
	Height	14cm

Issued Date: 07.02.2022

	Weight	1600gr
Assay Specification	Test channel	1
	Assay range	1-2500 Sec.
	Incubation temperature	37 + - 1
	Working time with full charge	8 Hour
	Battery life	2 Year
	Efficiency (Full Charge)	12 Hour (stand-by)
Power (AC/DC)		
	INPUT	220 v AC
	OUTPUT	18 v DC
Environment Temp.	15°C-30°C	
Humidity	%40-%70	

Electromagnetic Compatibility (EMC)

Accreditation n	0:	AB-1532-T
Tested item	:	CompactOne 9 ACT test device
Test report No	:	EMC20-0226
Tests	:	TS EN 60601-1-2: 2016
		EN 60601-1-2: 2015

Low Voltage Directive (LVD)

Accreditation n	0:	AB-1532-T
Tested item	:	CompactOne 9 ACT test device
Test report No	:	LVD20-092
Tests	:	IEC 60601-1:2005,
		COR1:2006,
		COR2:2007,

AMD1:2012

INSTALLATION

Working Area

Before unpacking the system, determine where the system will be placed. You will need a flat Field about 25 cm deep and 25 cm high. There should be no magnetic field near 30 cm. Open the box by following the directions and labels on the device box. According to the regional conditions, if the transportation is carried out under 10°c and over 40°c local climatic conditions, leave the box for 1 hour at room temperature.

UNPACKING

1. Open the carton

2. Examine the box and device components for damage when unpacking. If damaged, contact your carrier or service representative immediately.

3. Place the device in its place.

4. Remove from its protective packaging.

5. The box is checked to make sure all components have been removed from the box. The materials expected to be in the box are listed below.

a.	Hemonart CompactOne 9 Whole Blood coagulation system	1 pcs
b.	AC/DC power adaptor	1 pcs
c.	Power cord	1 pcs
d.	User manual	1 pcs
e.	PC connection line	1 pcs

Materials Required, but Should Be Purchased Separately

-	Electronic Quality Control	1 pcs
-	Test tubes	As required
-	Liquid Quality Control	As required

Connection of external devices

The device can be used with computer and printer. Connection ports are located on the back of the device.



Figure 2 connection ports

CAUTION: While making the connections, make sure that the power cables of all devices are not plugged in or are turned off.

Printer Connection

Set the printer communication parameters to 9600 baud rate with no parity, 8 data bits and 1 stop bit, using the XON / XOFF 3-wire software protocol. No special preparation is required when connecting a parallel printer. For additional information, contact HEMONART Technical Support team.

- 1. Obtain a printer cable (not supplied).
- 2. Connect one end of the printer cable to the port marked PRINTER.
- 3. Connect the other end of the printer cable to the printer.

Connecting to a Computer

The system can be connected to any computer using a standard NULL modem cable.

- 1. Get RS232 cable (1 piece comes with the device).
- 2. Connect one end of the cable to the port marked COM (Figure 2)

3. Connect the other end of the cable to a serial communication port not used on the computer.

Charging the Battery

The system battery must be charged before the system can be used.

1. Connect the plug of AC / DC Power Module to a power outlet.

CAUTION: Make sure that the AC / DC Power Module input voltage requirements match the voltage used in the laboratory.

2. Connect the AC / DC Power Module cable to the Power connector

3. Leave the battery charged for at least 16 hours.

Note: AC / DC Power Module can stay connected permanently.

BATTERY PRECAUTION

If you are not an authorized service personnel do not open the device. The nickel cadmium battery of the device is not user replaceable. Opening the device, attempting to change the battery will void the warranty and / or maintenance contract.

The Hemonart CompactOne 9 device is designed to operate safely with the nickel cadmium battery pack supplied by HEMONART.

Only authorized service centers can change the battery pack (Contact HEMONART Medikal Sistemler Sanayi Ticaret A.Ş.)

The battery pack should only be charged with the power supply provided for use with the Hemonart CompactOne 9 device. See the Charging the Battery section for instructions. The battery pack may get warm during charging. It's normal.

See the instructions in the Battery Care section to avoid shortening the battery life.

Should the battery pack leak, do not get the leaked liquid in contact with the skin or eyes. If contact occurs, wash the affected area with water and seek medical advice. If the battery leaks or does not work properly, please contact the manufacturer to arrange a service appointment for the device.

Follow local regulations for nickel cadmium batteries if they must be disposed of. Dispose of in accordance with legal requirements.

Low Battery Alert

The battery provides power when operated without the AC / DC Power Module. The device operates on a fully charged battery for at least eight hours.

When the battery is used to operate the system, the remaining charge is displayed as a numerical percentage or bar display. The message CHARGE BATTERY is displayed and the battery power display blinks when the battery power drops to 30 percent of full charge. The system can continue to be used when the battery power drops to 10 percent.

When the battery power drops to 10 percent of full charge, the message BATTERY TOO WEAK TO RUN TESTS is displayed. The message SHUTDOWN IN XX SECONDS starts to be displayed 30 seconds before the system shuts down automatically.

PRE-HEATING

On command, the test well can be preheated to 37 $^{\circ}$ C ± 0,5 $^{\circ}$ C. The test is started for preheating and the warming process of the test well continues for 1 minute.

Note: See the instructions for preheating requirements.

Auto Close

When operated from the battery, the system automatically shuts down after 30 minutes of inactivity. This 30-minute interval cannot be changed. When powered from the AC / DC Power Module, the system

will automatically turn off after a period of inactivity defined by the administrator. All data stored after automatic shutdown is stored.

Ending Test

The test is terminated if no clot formation is detected within 1200 seconds after the test is initiated. Then, the message FAULT> 1200 displayed and stored in the database indicates that the test result is outside the specified range.

Note: Results beyond the specified time are outside the sensitivity range of the test. These tests should be repeated immediately and, if verified, reported above the maximum time.

The test is terminated automatically if no test tube is inserted into the well within 60 seconds after the START key is pressed.

KEYPAD

The device has an On / Off button under the test well in the front panel, and has Touch Screen Menu management icons on the screen for all other operations.



Figure 3: KEYPAD-SCREEN

Key descriptions

KEY	PURPOSE	
	Power on/off	
Play Button	Start to test or to access the submenu	
Lock Button	Used with the permission of authorized operator to access the	ne menu.
STOP Button	It is used to save the operation and command.	
icon	It is used to access submenu and sub line.	
+ icon	It is used to access upper menu and upper line.	
UM-001	Issued Date: 07.02.2022	Rev No: Rev01

USER INTERFACE



Figure 4: User interface, test channel interface

Press the START button to start a test in the well. Press the Lock button and then press the stop button to cancel the test. The test will be canceled.

Note: Pressing the Square (STOP) button closes the test, all related menus are removed, and the test is not stored in the memory.

Note: If ACT is running, information and results about the test are displayed in the middle of the display panel.

When the device is on, the screen is fully illuminated during operation. The screen illumination is fixed. When the battery is used, the percentage of battery power remaining is displayed as a numerical percentage and a horizontal bar indicator in the upper left corner. AC / DC Power Module is used for Charge (18v 3.5amp).

Setting Time

The time a test is performed is automatically recorded along with the test result. Time format is 24 PM

1. Activate the cursor transitions on the screen by touching the lock button.

2. Touch the (HH / MM) section you want to edit on the clock display on the screen,

3. When you see the red color cursor under the icon you touched, touch the minus and plus keys at the bottom of the screen and enter the correct hour or minute by changing the numbers to lower and upper values.

4. After entering the correct time using the plus and minus keys, press enter / arrow key located at the left top of the keypad under the screen and save the time.

*003 19	/09/2020 15:12:13	Previous	test	
INS	36.9°C	Current	test	
UID:	0012			
PID:	0012			
• •		-	+	<u>×</u>

Figure 5: Red line on date/time screen

Setting the Date

The date a test is performed is automatically recorded along with the test result.

1. Activate the cursor transitions on the screen by touching the lock button.

2. Touch the (dd / mm / yy) part you want to edit on the date display on the screen,

3. When you see the red color cursor under the icon you touched, touch the minus and plus keys at the bottom of the screen and enter the correct date by changing the numbers to lower and upper values.

4. After entering the correct time using the plus and minus keys, press the enter / arrow key located at the left of the keypad under the screen and save the date.

Patient Identification

PID information can be entered while running a test if desired. (Patient barcode information)

1. Activate the cursor transitions on the screen by touching the lock button.

2. Tap on the PID index read on the left side of the screen.

3. With the appearance of the red cursor, numeric number icons will also appear on the right side of the screen.

4. Define the PID you want to enter by touching the number icons.

5. Press enter / arrow key on the bottom of the screen to save, the device will save the data.

*004	.9/09/2020 15:17:06	Previ	ous	test		-
NS	36.9°C					
UID:	0012	1	2	3	4	5
PID:		6	7	8	9	0
به =				4		¥

Figure 6: Red line cursor on PID area

PID defined patient test is stored in the device database with PID data, time, date and ACT result after the test is completed.

User Identification

UID information can be entered, if desired, while running a test. (User credentials)

- 1. Activate the cursor transitions on the screen by touching the lock button.
- 2. Tap on the UID directory read on the left side of the screen.

3. With the appearance of the red cursor, numeric number icons will also appear on the right side of the screen.

- 4. Define the UID you want to enter by touching the number icons. (Max 11 characters)
- 5. Press enter / arrow key on the bottom of the screen to save, the device will save the data.



Figure 7: Red line cursor in UID area

Previous Test

The Previous Test icon is fixed in the upper right corner of the screen to follow and remind the previous test. Data information of the previous test saved in this icon frame can be viewed. When the new test is completed, the results of the new test are automatically processed and tracked into the previous test framework.

8003 01/ 8003 0	/01/2019 00:07:04 36.9°C	Previous Current	test test			Data from previous test
UID: PID:	0					
• •			÷			
			Сотра	actONE	9	

Figure 8: Previous Test data screen

Temperature

Each tube is heated to the average patient temperature (37 $^{\circ}$ + -1). In order to monitor the temperature of the tube well, the temperature indicator can be watch in the upper left part of the screen.



Figure 9: Temperature area

NS (Coagulation Status monitoring)

Hemonart CompactOne 9 device allows the sample placed in the device for ACT test to digitally detect the fluidity of the sample in the temporal direction that goes to coagulation with the start of the test and allows the stages of coagulation formation to be visually followed by the gradual change of the NS icon on the screen from black to red.

When the coagulation formation is complete, the result is displayed on the screen both numerically in seconds. Also, the steps can be followed until the coagulation tendency occurs via the NS icon.



Figure 10: NS area

Current Test

Following the flow of the starting test in seconds, the Hemonart CompactOne 9 device also counts numerically with a distinct spot on the screen. You can follow this count in seconds numerically in the Current Test frame. When the test is completed, counting stops on the screen and a warning beep is heard. The value on the screen gives the clotting time.



Figure 11: current test monitoring

Printer

To connect the system to an external parallel printer, the RS232 com port on the back of the device must be used.

Records in the system database can be printed with Serial port printer.

Call Hemonart technical service for detailed information and technical support.

Note: An external printer must be used to print the database.

Note: The printout is IBM Layout (PC-8) standard. Enabling Data Logging the data logging feature is used to send raw data obtained during an exam to an external computer or printer.

OPERATION

After the device is charged, a test can be run on the system at any time. However, it is recommended to enter the correct time and date and set configuration preferences before running tests.

Note: Read the headings al under the heading Display for instructions on correct date-time entry and device configuration.

Power on the instrument

O Press the START key and wait for 1 second. The interface visual appears on the screen by turning on the screen illumination.

Well Preheating

Some tests require preheating before the blood sample is added.

Note: For the required preheating time, refer to the individual test instructions for use.

Press the Arrow / Start key on the instrument screen to start the test for preheating without tube insertion into the well. This preheat test will take 60 seconds and will stop after 60 seconds. This 60-second preheating can be repeated until the well is raised to the desired temperature.

Starting the Test

1. Inject the sample into the test tube through the syringe and simultaneously press the START key.

The timing (counting) of the test begins after the beep to indicate the start of the test.

2. Slightly invert the tube up and down for 5-10 seconds to mix the reagent and sample.

3. Put the test tube to the well (Figure 12 below). Quickly rotate the tube one turn clockwise.

Note: After pressing the START key, the operator can enter the PID, UID. Other functions are not active until the test is completed.

4. While the instrument confirms that the magnet moves freely in the tube, the counting numbers continue to change in red. Once verified, the numerical counting values turn black and displayed on the normal screen.



Figure 12: Testing

Checking Results

While a test is running, the test name, temperature, PID (if entered) and time since the start of the test are displayed. NS (Coagulation Formation) trend can also be followed in the configuration screen

When clot formation is detected, the device beeps and the name of the test and clotting time (seconds) are displayed. Results are displayed until the tube is removed from the well or the CANCEL or START key is pressed.

Power off the instrument

Press and hold the START button to turn off the system.

When external power is used, the device automatically turns off after 60 minutes of inactivity.

When using battery power, the device automatically turns off after 30 minutes of inactivity.

QUALITY CONTROL

It is recommended that medical and laboratory devices be enrolled in an adequate quality assurance program to maintain the correct and reliable performance of the equipment. All records of this quality control should be kept.

Routine quality control tests should be part of a comprehensive quality assurance program.

These tests should include:

1. Testing system performance using Electronic System Verification tube or LQC (CCT).

2. Test tube reagents for each assay using two levels of liquid control in accordance with the Instructions for Use.

Auto Control

The Hemonart CompactOne 9 device performs an "automatic check" each time it is activated and a test is performed.

When a test is started, the system checks are performed automatically and perform the following:

1. Verification that the battery power is sufficient to complete a 1500-second test.

2. Verifying that a tube is attached and the test well is functioning properly. If the return or temperature parameters are not suitable, the test is terminated.

3. Verifying that the test well is heated to 37 $^{\circ}$ C ± 1.0 $^{\circ}$ C. If this temperature is not reached or exceeded, the test will be blocked.

4. Verifying that the internal timers are working correctly for each test. At the end of the test, if the system timer and the exam timer do not match, the test result is not reported.

ACCESSING THE QC PROCEDURE

PID or UID data can be noted by developing a separate coding system for quality control tests, and quality tests can be selected through the Quality control code when transferring data to an external device.

QC WITH EQC SYSTEM

The device must be tested at two levels before each shift in which the device is used. EQC (Electronic Quality Control) tube can be used or LQC (Liquid Quality Control) products can be used to provide three levels of electronic device verification regarding device performance. EQC Stick can be purchased separately.

Not: If QC results are not in their range please contact technical service.

Liquid QC

The device can be tested at any time using LQC products.

Biochemical blood coagulation mixtures independently developed to provide quality control tests of bedside devices are used for fluid control verification. It is recommended to use two types of verification, normal and abnormal, before each shift. A usual patient test procedure is applied by mixing the contents of the two solid and liquid tubes and injecting them into the ACT tube. It is observed whether the results are within predetermined ranges.

Note: For results that do not fall within the specified range, call Hemonart technical support.

PRECAUTION BEFORE OPERATION

DO NOT open the device as there are no user-serviceable parts otherwise warrant will not be valid.

DO NOT pull the AC / DC Power Module out of the device by pulling on the cable. DO NOT use tubes that have expired or that have not been stored properly.

Use ONLY tube brands that have previously been clinically studied with the compactone 9 and have been approved for use.

DO NOT force the tubing into the device. If resistance is encountered during insertion, gently remove the tube and examine the tube well. Remove any obstacles before trying to use the device again

DO NOT use excessive force when pressing the device keys.

DO NOT expose the device to extreme temperatures (above 50 ° C).

DO NOT drop the device and do not use the results if the device drops during the test.

Using any AC adapter other than the supplied one may result in a decrease in the safety level or damage to the device.

Using the accessory equipment described in this manual around the patient or in environments that do not comply with the equivalent safety requirements of this equipment or the IEC 61010 standard may result in a decrease in the level of safety in the system.

Caution: Use this device in accordance with the instructions given in this manual. It is not recommended to use the device by an operator who has not received training.

The Hemonart CompactOne 9 device should only be used by healthcare professionals trained and approved in the use of the system in accordance with hospital policies and procedures.

All biohazard safety guidelines regarding the use and disposal of human blood must be strictly followed when collecting and handling blood samples and when operating the Hemonart CompactOne 9 Whole Blood Coagulation System.

Used Hemonart test tubes should be considered potentially infectious. Tubes should be handled in accordance with institutional policies regarding the disposal of potentially infectious material.

Hemonart CompactOne 9 test results should always be reviewed in accordance with the specific patient's condition or anticoagulant therapy. Tests that yield test results that are inconsistent with the patient's clinical condition should be repeated or supplemented with additional diagnostic tests.

LIMITATIONS

Inappropriate techniques used during blood collection and sample processing affects the test results of the Hemonart CompactOne 9 Whole Blood Coagulation System. The accuracy of the test is highly dependent on the quality of the blood sample.

RESULTS

Summary

2000 patient test results are stored for the test well in the device database. In addition to the test results, the date and time of each test, PID (if entered) and UID (if specified) are also stored. Stored results can be transferred to external media for viewing, viewing and printing. When printing test results, the results of the last test or the entire database containing patient results can be printed.

Note: Verify that all third-party connectivity software to be used is compatible with the software version of the Hemonart CompactOne 9 device being used. Transferred data will be lost when third-party connectivity software is used with incompatible versions of the Hemonart CompactOne 9 software.

Processing Records

PID and UID records made for tracking patient tests can be accessed again with the integration of the device to the office or personal computer and the desired test can be monitored.

For this process; follow the instructions below.

The speed of transferring data to an external source through COM Ports can be specified.

1. Verify that the external source is properly connected to the Hemonart CompactOne 9 port.

2. Select the Hemonart CompactOne 9 port from your computer's connector ports menu.

3. Open the Hemonart CompactOne 9 file on your PC as a text image.

Printing Results

The entire database containing the results of the last test or patient results can be printed. **Note:** An external printer or computer is required to print the database.

DEFAULT SETTINGS

Factory default settings of the Hemonart CompactOne 9 system are listed below:

Test number	: PAT=12-13 tests over 500sec. with %100 battery
Battery warning	: % 10
COM Port	: YES
Log Data	: YES
Enable FF	: YES
СОМ	: 9600 Baud rate
Automated shutdown On AC power	: 60 min
Shutdown on battery	: 30 min
Lang.	: ENGLISH
Time interval	: 24 hour
Date	: DD/MM/YYYY
PID	: Unknown
UID	: Unknown
PID Digits	: 11
UID Digits	: 11
NS	: Yes
Time	: ON
Start Date	: 01/01/19

TROUBLESHOOTING

UM-001

Error Messages

The danger and error messages that can be displayed while operating the system are listed in the table below. The hazard / message, probable cause and corrective action are shown for each message. You can contact Technical Support by phone at + 90 2165929922 or by e-mail at <u>info@hemonart.com</u>.

Attention:

Only Hemonart service engineer authorized to repair instrument. In case of technical failure or periodic maintenance of the instrument, please, contact our staff at the address above.

Warnings and Corrective Action

- If the device cannot be turned on outside the network, the battery is not working. The system can only be operated with the provided transformer. The battery must be replaced. Contact Technical Support for repair.
- If the battery indicator is less than 10%, the battery is depleted. Charge the battery for 16 hours or temporarily use AC power.
- Temperature indicator is below 36 ° C or above 38 ° C. Well temperature did not reach 36.5°C or exceed 38.0°C. Turn the system off and on again to clear the error. Repeat the test with a new test tube. The well is thermally fused to protect the heater. The fan must be turned on while the device is operating on the AC / DC Power Module. If the message continues, contact Technical Support.
- If the tube does not rotate or is spinning slower than usual a malfunction in the well motor has been detected. Correct test rotation cannot be maintained. Contact Technical Support.
- Test failure, the test was completed and the magnet was removed before it was stable for the required time. The test is stopped and the record of the aborted test is stored. Repeat the test with a new test tube.
- If the tube does not turn, tap the tube and spin in the well.
- > 2500s the test time has exceeded the maximum time of 2500 seconds or the well collar is broken and the test tube will not rotate. If the well rotates the tube, repeat the test with a new tube assay. The record of the test is saved in the database.
- The test stops after 60 seconds, although there is a tube and a blood sample. The magnet sensing sensor of the well has malfunctioned. Call technical support.
- If the test failed with the start command or the tube was placed in the well, there was a malfunction in the well drive motor or an electronic problem occurred in the well. The test cannot be run. Contact Technical Support.
- Data not being transferred or printed, an error condition has occurred in the external PC or printer. For help, see the printer User's Guide.
- A timeout occurred during data transfer on COM, COM port. Check the cable connections of the port. If there is no problem with the connections, the reason why data transfer stops at the port should be determined.

MAINTENANCE

CLEANING

It is recommended that equipment be cleaned and decontaminated prior to service or transfer.

Clean the surface of the device and the LCD screen with a cloth dampened with a 10% dilution of bleach in water. To remove residual disinfectant from plastic surfaces, wipe the device with a cloth moistened with water.

Caution: Do not use wet towel. Use damp towel

Clean the test well with a cotton swab moistened with 10% bleach dilution in water. After cleaning, use a dry cotton swab to make sure there is no liquid on the bottom of the test well.

Note: Follow this procedure before sending the device to the service center.

Do not use piercing, cutting or melting material on the device for maintenance and cleaning.

In case of overheating, smoke or noise that may occur in the device, turn off the power and ventilate the room where it is located. Follow the instructions provided by notifying the technical support team.

Disposal of the Device

The useful life of the device is foreseen as 15 years. If disposal is required, follow local regulations for disposal of electronic devices and NiCD battery packs.

TECHNICAL SPECIFICATIONS OF PERIPHERAL UNITS

Prepare Serial Cable for External Printer Connection

Configure the RS232 cable as shown below:

Connector Size / Type: RS232 Port 9 pin female

Type D metallic plastic shell

Pin Assignments:

Pin Color Code Signal Function

1 Not used

2 Blue * TX Data Transmission

3 Black * RX Data Acquisition

UM-001

4 Not used

5 White * Earth

6 Not used

7 Not used

8 Not used

9 Red * + 5VDC Power for scanner

Shell Braid Evacuation Shield (EMI / RFI)

* Colors according to printer specifications



Figure 16: Printer connection schematics



HEMONART Medikal Sistemler Sanayi Ticaret A.Ş.

Address: Alacaatlı Mah., Şehit Hayrettin Erem Cad., No:24/AF,06810 Çankaya/Ankara TURKEY

Tel: +90 216 5929922

<u>info@hemonart.com</u>

www.hemonart.com

EC REP

Eucerep B.V. Roald Dahllaan 33, 5629MC, Eindhoven, The Netherlands