

HUMASed 20

USER MANUAL

Random Access Autoanalyzer
for the Determination of the Erythrocyte Sedimentation Rate (ESR)



Cat.-No.: 16020/1



Human

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1 INTRODUCTION

This manual is considered as a part of the instrument; it has to be at the operator's hand as well as at the maintenance operator's availability. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid instrument or personal damages, carefully read the "GENERAL SAFETY WARNINGS", describing the suitable operating procedures. In case of breakdowns or any troubles with the instrument, apply to the local Technical Service.

1.1 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 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, diskettes, 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.

HUMAN shall be relieved of any obligation under this warranty, unless a completed installation / warranty registration form is received by HUMAN within 15 days of installation of this product.

This warranty does not apply to damages incurred in shipment of goods. Any damage so incurred shall be re-reported to the freight carrier for settlement or claim.

1.2 Intended Use of the Instrument IVD

The instrument has to be used for the expected purposes and in perfect technical conditions, by qualified personnel, in working conditions and maintenance operations as described in this manual, according to the

GENERAL SAFETY WARNINGS. This manual contains instructions for professional qualified operators.

1.3 General Safety Warnings

Use only chemical reagents and 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 stationary flat working surface, free from vibrations.

Do not operate in area with excessive dust.

Work at room temperature and humidity, according to the specifications listed in this manual.

Do not operate this instrument with covers and panels removed.

Only use the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.

Use only the fuse type and rating specified by the manufacturer for this instrument, use of fuses with improper ratings may pose electrical and fire hazards.

To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power the instrument in potentially explosive environment or at risk of fire.

Prior to cleaning and/or maintaining the instrument, switch off the instrument and remove the power cord.

For cleaning use only materials specified in this manual, otherwise parts may become damaged.

It is recommended always to wear protective apparel and eye protection while using this instrument.

Respective warning symbols, if appearing in this manual, should be carefully considered.

1.4 Disposal Management Concept

The currently valid local regulations governing disposal must be observed. It is in the responsibility of the user to arrange proper disposal of the individual components.

All parts which may comprise potentially infectious materials have to be disinfected by suitable validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal have to be carefully observed.

The Instruments and electronic accessories (without batteries, power packs etc.) must be disposed of according to the regulations for the disposal of electronic components.

Batteries, power packs and similar power source have to be dismantled from electric/electronic parts and disposed off in accordance with applicable local regulations.

1.5 Instrument Disinfection

Analytical instruments for in vitro diagnostic 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.

Before doing 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/disinfected. Decontamination/disinfection should be performed by a authorised well-trained personnel, observing all necessary safety precautions. Instruments to be returned have to be accompanied by a disinfection certificate completed by the responsible laboratory manager. If a disinfection certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre, or from authority's interventions.

1.6 Notice

Every effort has been made to avoid errors in text and diagrams, however, HUMAN GmbH assumes no responsibility for any errors which may appear in this publication. It is the policy of HUMAN GmbH to improve products as new techniques and components become available. HUMAN GmbH therefore has to reserve the right to change specifications if necessary in the course of such improvements.

HumaSed 20 is a random access autoanalyzer for the in vitro diagnostic determination of the Erythrocyte Sedimentation Rate (ESR), able to process up to 5 samples simultaneously by means of an IR LED optical system.

HumaSed 20 requires minimal handling of the sample, as the test is directly performed in the test-tube, admitting both open and vacuum tubes.

HumaSed 20 allows the test to be run in:

1 HOUR/2 HOURS MODE (default setting)

or

1 HOUR/2 HOURS MODE with temperature conversion

In both cases, results are expressed in Westergren millimetres within only 12 minutes.

HumaSed 20 is capable of processing 25 samples per hour, with uninterrupted sample loading, as test positions are left free.

HumaSed 20 features structured software to facilitate its understanding and use, with a clear and precise display. The instrument requires very little user's intervention, and handling is simple and user-friendly.

2 INSTALLATION

2.1 Safety Requirements

Note: Under no circumstances should the user modify the safety features of the instrument deliberately. Any modification of the instrument will cancel the warranty or the technical service agreement, if available.

Should the cable or the power supply begin to look damaged or broken, replace them immediately.

This instrument is an electromechanic device. Do not handle the internal parts. For any technical issue, contact your distributor's technical service, whose staff is trained and qualified to carry out any repairs.

WARNING: The instrument must be disconnected from the power supply before starting any technical corrective work. Operators should not attempt to repair faults or breakdowns.

In case of accidental spillage of analysed samples, clean the spill immediately with an appropriate disinfecting solution to avoid possible contamination of the laboratory personnel and equipment.

Note: The Instrument may be cleaned with a water and soap solution or with 70% alcohol. Do not use a higher alcohol concentration to prevent damage of the cover.

2.2 Instrument Requirements

The **HumaSed 20** must be placed on a **perfectly flat and level surface not exposed to any vibrations**. It is important to leave enough room (about 15 cm) for proper air circulation in the rear of the instrument.

Weight : 1 kg.
Width: 14 cm.
Height: 16 cm.
Depth: 16 cm.

Main voltage: input 100V –240V AC and output 5V CC
Frequency 47-63 Hz
Frequency line variation +/- 2 Hz
Current 0.5 A
Energy consumption 10 VA

The **HumaSed 20** is designed to operate under certain environmental conditions:

Room temperature 15...32°C
Max. relative humidity 80% at 32°C

2.3 Transport

The packing of the **HumaSed 20** (Weight: 1 kg. Dimensions: 29x29x25 cm.) contains: instrument, power supply with cable, user's manual.

Prior to the installation of the equipment, a visual packing inspection is recommended in order to detect any abnormality that could affect the instrument. If any problem is observed, notify the supplier before accepting the unit.

If it is necessary to prepare the instrument for transportation, let it operate (without any test cycle running) for at least two minutes. After this time, the reading plate will automatically be switched to a safety position, so that the equipment can be turned off and transported safely.

2.4 Installation

Place the instrument in its final location.

Make sure the mains cable is properly connected to the power socket (2). Start the instrument with the power switch (3) located on the left rear.

The device will be checked for about 1 minute and the main screen will be displayed.

3 DESCRIPTION

3.1 Instrument Description

The **HumaSed 20** has been designed to operate, without needing an adapter, with non vacuum tubes containing a sodium citrate solution as anticoagulant. The **HumaSed 20** is a closed system. Only HumaSed Tubes (Cat. No. 16041 / 16042) can be applied. The capacity of the working shelf is 5 sample positions. The test cycle time for every sample is 12 minutes for 1H and 2H values. In both cases results are expressed in Westergren millimetres. System throughput is 25 samples per hour. The basis of the system allows for random access of samples, so that the analytical cycle starts once a sample tube is inserted. So there is no need for loading all 5 working positions to start an analytic cycle. When the test time for a sample is completed, the corresponding values will be displayed and sent to a peripheral unit (computer system or printer) via on-line connection.

The instrument allows the user to connect a printer to the serial connector.

3.2 Tubes

The **HumaSed 20** is a closed system. Only HumaSed NON-VACUUM or HumaSed VACUUM Tubes can be applied.

Specifications

REF	16042
Packaging:	400 Tubes /box
Material:	Glass, 13 X 75 mm with safety cap
CITR	Trisodium Citrate (1:4) Concentration: 0.129 mol/l
Stability:	Stable up to the expiry date indicated on the label when stored as recommended
Storage:	4...25°C.
Product use:	Measurement of Erythrocyte Sedimentation Rate in whole blood.
Sample volume:	1.6 ml
Robustness:	When centrifuged, will withstand an RCF (Relative Centrifugal Force) of 3000 g along a longitudinal axis

Product Use Precautions

1. All glass materials are breakable; exercise caution while handling.
2. Handle all biological samples and blood collection devices (lancets, needles, luer adapters, and blood collection sets) in accordance with the manufacturer's instructions
3. Transfer of a sample from a syringe to a tube is not recommended. Additional manipulation of sharp needles increases the potential for needlestick injury. Also, depressing of the syringe plunger during transfer can create pressure, possibly forcefully displacing the stopper and sample and causing potential blood exposure. Using a syringe for blood transfer may also cause over- or underfilling of tubes which may result in an incorrect blood-to-additive ratio.
4. Use HUMASED vacuum tubes before the expiration date indicated on the box and tube labels.
5. Since HUMASED blood collection tubes contain a chemical additive, it is important to avoid possible backflow from the tube. To protect against backflow, observe the following precautions:
 - (1) Place patient's arm in a downward position.
 - (2) Hold tube with the stopper uppermost.
 - (3) Release the tourniquet as soon as blood starts to flow into tube.
 - (4) Make sure tube contents do not touch the stopper or end of the needle during venipuncture .
6. DO NOT REMOVE THE TUBE STOPPER UNDER ANY CIRCUMSTANCES.

Specimen Collection:

1. WEAR GLOVES DURING VENIPUNCTURE. GLOVES MINIMISE HAZARD EXPOSURE.
2. Mount the needle in the holder. Be sure needle is firmly seated to ensure it does not loosen during use.
3. Gently tap tubes containing additives to dislodge any material that may be adhering to the stopper.
4. Place the tube into holder. Do not puncture stopper of tube yet.
5. Select site for venipuncture.
6. Apply tourniquet. Prepare the venipuncture site with an appropriate antiseptic.
DO NOT TOUCH THE VENIPUNCTURE AREA AFTER DISINFECTION.
7. Place patient's arm at a downward angle.
8. Remove the needle shield.
Perform venipuncture WITH ARM AT A DOWNWARD ANGLE WITH THE TUBE IN A VERTICAL POSITION.
9. Push the tube onto needle, puncturing stopper diaphragm.
Center the tube in holder when penetrating the stopper to prevent sidewall penetration which could result in premature vacuum loss.
10. REMOVE THE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE.
DO NOT ALLOW THE CONTENTS OF TUBE TO CONTACT THE STOPPER OR END OF THE NEEDLE DURING THE PROCEDURE.



Note: Always observe common precautions to minimise hazards.

Note: If no blood flows into the tube, or if blood ceases to flow before the required volume of specimen is collected (1.6 ml), the following steps are suggested to complete satisfactory collection:

- a. Push tube downward until tube stopper has been penetrated. If necessary, hold the tube in place to ensure a complete vacuum draw.
- b. Confirm correct positioning of the needle cannula in the vein.

c. If multiple sample needles are used, remove the tube and replace it with a new one

To ensure proper performance, the HumaSed VACUUM TUBES must be inverted and returned to an upright position 8 - 10 times before being inserted into the HumaSed 20/40.

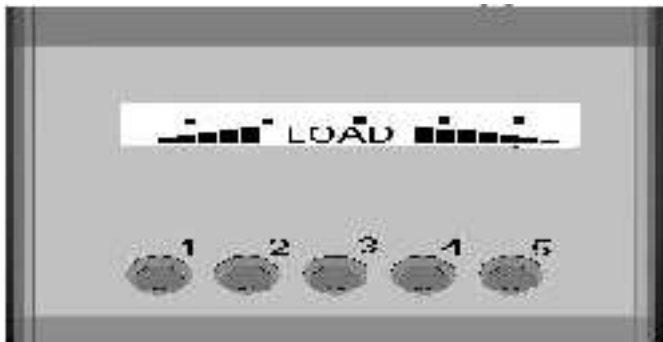
3.3 Control Panel

Located under the working shelf, a 24x2 display.

3.3.1 Display

The HUMASED 20 is equipped with a backlight LCD of 24 x 2 digits. The status and the final results of every position are displayed.

3.3.2 Working Shelf

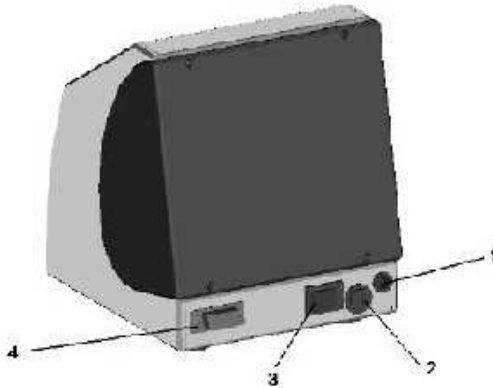


5 Sample slots are located underneath the display.

3.4 Rear Connector Panel

The following devices are located in the rear:

1. Power inlet (1).
2. Fuse holder (2).
3. Power switch (3).
4. SUB-D9 connector (female) for on-line/printer connection (4).



4 OPERATION

4.1 Switching-On the Unit

Switch the unit on using the power switch (see 2.3). For about 1 min. the display will flash “TEST” in both rows while the electronic and mechanical components are checked.

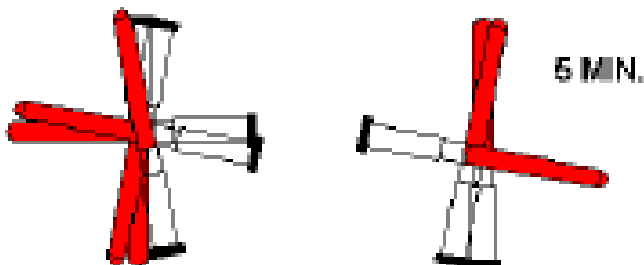
The instrument does not hold backup memory. When the instrument is turned off, the results of the last analysis will be lost. The instrument is now ready to start an analysis cycle. If the instrument detects a tube during this phase in one of the sample positions, the “**EXTRACT**” message will be displayed. **Then the user has to remove that tube first.**

4.2 General

Fill the tubes exactly up to the **level** mark on the tube.

The required volume is approx. 2 ml. The tolerance of the equipment with regard to the level is **+5 mm and -20 mm**. Otherwise, the instrument will display an “**L.E.**” level error message.

Shake the sample by slowly inverting the tube for approximately 5 minutes, before inserting it into the instrument.



The test starts when the tube is inserted in the instrument. **Do not remove the tube from its position until the test is completed.** Otherwise the test will be aborted and the “**S.E.**” error message will appear on the results printout.

12 minutes after starting the test, the **end of the test** is reported displaying the **1H results** in the first line and the **2H results** in the second line in the corresponding position of the display. These results stay on the display until another tube is inserted into that position

4.3 Status Displays

On the main screen, the following message is displayed:



The status of the working shelf is displayed. The dot “.” indicates that this position is empty (no tube detected); a **black square** “■” or “**RUN**” in the second line indicates that **this position is in use** (the height of the black square decrementing by minute to show the remaining time for the respective analysis); a number means a result (1H in first line, 2H in second line) and indicates that the **test has finished** in this position; “**E**” indicates an **error message** (see Section 4 – error messages).

Example:

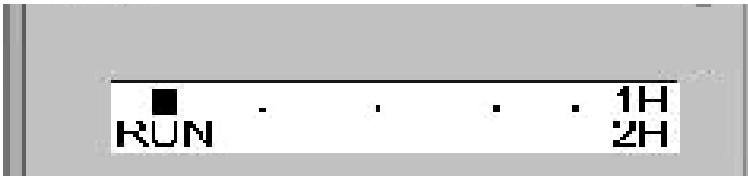


In this case, position 1 has ended, position 2 presents an error, positions 3 and 4 are in use (3 almost ending and 4 just at the beginning of the analysis time), and 5 is empty.

This display is updated approx. every minute and whenever the user returns from the menu. That is, approximately every minute newly detected and finally analysed tubes appear on the display.

4.4 How Work

Switch on the unit (see section 3.1) and wait until the end of test cycle. When a dot “.” appears in a certain position load this position with a new tube (first shake the tube as described in section 3.2). The “LOAD” message appears when the instruments does not detect samples in any position.



When this sample is recognised by the instrument with the **black square** “■” in the first line , and “RUN” in the second line, the sample starts the analysis cycle.



With every reading cycle the **black square** “■” gets smaller to indicate the remaining analysis.



At the end of analysis the instrument displays two numbers. These numbers mean a result, (67) 1H in first line, (128) 2H in second line. At the same time the instrument sends the results to a printer or computer via the serial port.



The sample can now be removed. When a dot “.” appears, this position can be reloaded with a new tube.

Note: It is very important to wait until a dot “.” is displayed for a certain position, indicating that the instrument recognised this position empty and another sample will be accepted.

Note: Do not forget to mix the samples properly.

The analysis results stay in their display position until a new sample is loaded or the instrument is switched off.

Data can be transmitted to the computer system of the laboratory. So it is necessary to know the communication protocol (Section 5 of this Manual).

Data can also be transmitted to any computer with a free serial port, only adjusting the port parameters (section 5) on the **HyperTerminal** program and printing from this program.

5 ERROR MESSAGES

5.1 Errors

1. "L.E" Level Error

It indicates that the blood level is not correct.

Fill to the correct level and repeat the test.

If this error message is displayed for a position with no sample tube, call technical service.

2. "S.E" Sample Error

It indicates that a sample has been removed before completing the test. Repeat the test.

If this error message is displayed for a position with no sample tube, call technical service.

5.2 Analytical Errors

Low results:

- a. Possible blood clot in the sample. Repeat the test with a new sample.
- b. When more than 2 hours have elapsed from the sample collection until the test.
- c. Insufficient sample amount, altering the blood / anticoagulant ratio, affecting the test result.

High results:

- a. Sample not shaken correctly.
- b. If the Instrument has been installed on a surface that is not perfectly level. A 3% inclination can increase the ESR by 30%.
- c. Excessive sample amount, altering the blood / anticoagulant ratio, affecting the test result

6 ON-LINE COMMUNICATIONS PROTOCOL

6.1 General

The data is automatically sent at the end of the analysis.

6.2 Features

Are the same in the case of **THERMIC PRINTER** or in the case of **COMPUTER**.
One-way connection with a remote system.

DATA OUTPUT VIA RS232 9CTS FEMALE CONNECTOR

Note: For a correct functioning of the linkage and the Equipment it is very important that only these 2 pins are connected to the shortest coupling wire.

INSTRUMENT PINS

TX : PIN 3 (transmission)

GND : PIN 5 (ground)

PROPERTIES

BAUD RATE : 9600

DATA BITS : 8

PARITY : NONE

STOP BIT : 1

WITHOUT FLUX CONTROL.

6.3 Data Package Contents

The data transmitted are characters with some control codes.

HEADER (switch on instrument)

12h, 3Eh, 00h, 1Bh, 77h, 01h

Five lines of text followed by 0Dh.

And at the end 1Bh, 40h 1Bh, 4Ah, 9Fh.

AT THE END OF ANALYSIS

The instrument sends a package. This package contains 3 parts, one part with control codes at the beginning, one part with control codes at the end, and a part with one record for every sample sent by the instrument.

The initial control code are :

12h, 3Eh, 00h, 1Bh, 77h, 01h

Then the full record of every selected sample is transmitted.

Every sample record is composed of 18 BYTES followed by 0Dh. It is a text record and its format is as follows:

“ __POS_P__111__222” followed by 0Dh,

Where:

. “_” Equals a blank space = (20h).

. “POS” are 3 characters. It’s a text “POS”.

. “P” is the position in the work shelf (1 to 5).

. “111” is the sample result of the first hour (1 to 159) In the case of error “111” will be “E.S” or “E.L”

. “222” is the sample result of the second hour (1 to 159).

The last control codes are:

1Bh, 40h, 1Bh, 4Ah, 9Fh.45 HUMASED 20/01-02/01

6.4 Thermal Printer

Connect the **Thermal Printer** to the power supply. Connect the serial cable of the **Thermal Printer** to the online connector of **HumaSed 20**. Switch on the printer. And now the printer is ready to work.

Note: Remember to switch off the printer when you finish work.

Note: The Thermal Printer works with thermal paper only. If the user loads another kind of paper, possible DAMAGES are not covered by guaranty.

7 SERVICE

7.1 General

The instrument has been designed to last several years with only a minimum of maintenance, although some factors could influence the duration of this period.

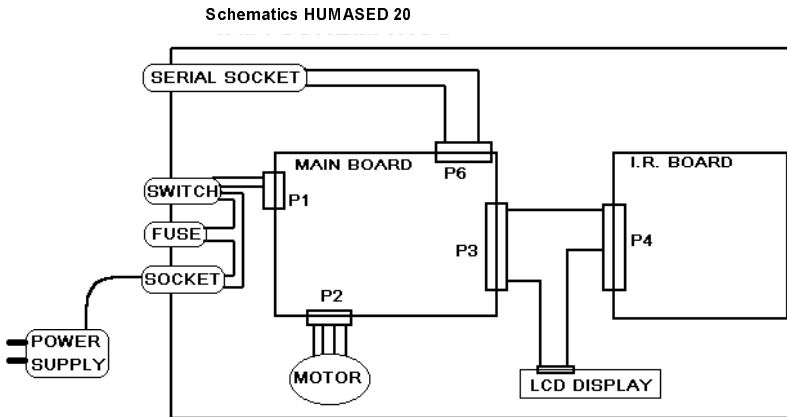
- The instrument has to be operated in a clean ambience and low dust environment. Dust could be adhere to the reader and movable parts of the machine. Cover the instrument when not in use.
- Clean the instrument with a humid cloth, when needed.
- Avoid spilling of liquids or reagents over the equipment
- Avoid breaking of tubes.
- The stability of the mains in the laboratory affects the life-time of the electrical components of the equipment. Keep the instrument away from other devices generating electromagnetic disturbances, such as centrifuges, autoclaves, equipment not marked CE and, generally, equipment using electronic power devices such as motors, pumps, electrovalves and compressors.

7.2 Fuses Change

To replace the fuses, proceed as follows:

- a. Disconnect the instrument from the power supply and pull out the connector cable.
- b. Remove the fuse-holder from its housing by opening the interior (red) part of the fuse-holder with a suitable object (screwdriver).
- c. Remove the fuse.
- d. Substitute for 5x20 – 1 A. fuse.
- e. Put the fuse-holder back to its original place..53 HumaSed 20/01-02/01

7.3 Electronic Parts



The instrument consists of the reader and the external power supply.

The performance data of the power supply are:

- Main voltage: input 100V – 240V AC and output 5V CC
- Frequency: 47-63 Hz
- Current: 0.5 A
- Energy consumption: 10 VA

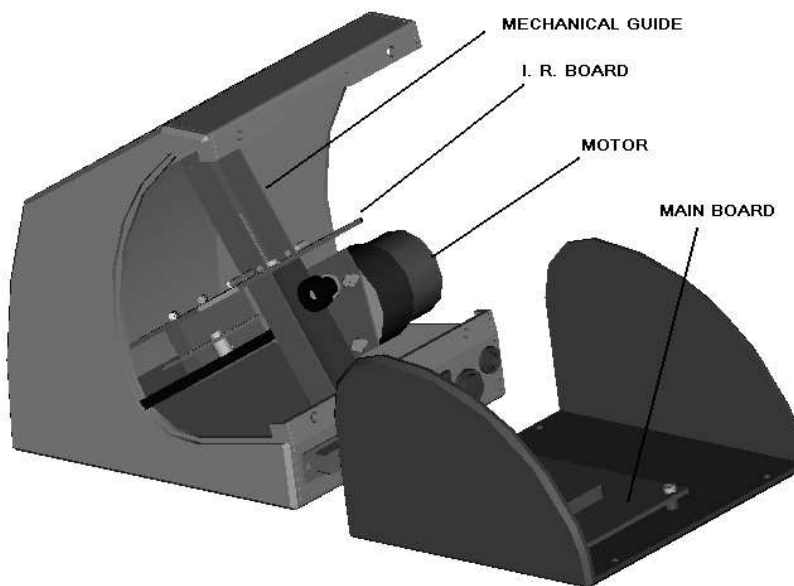
The power supply is connected to the instrument through a socket, followed by a fuse and a switch. The main board is located behind the switch. The socket, the fuse holder, the switch, and the serial socket can be found in the rear of the instrument.

The main board is placed in the back cover. The main board controls all functions of the instrument:

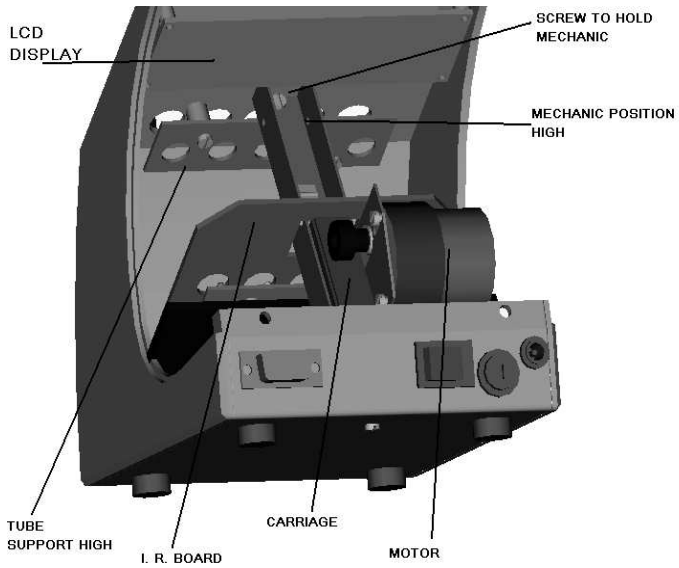
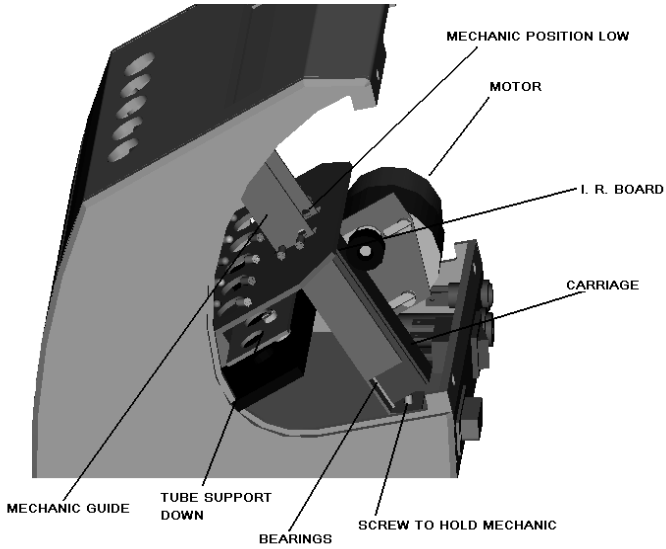
- The motor.
- The LCD display.
- The I.R. Board (reader and mechanic sensors)
- The serial port.

The temperature sensor is also located on the main board.

The I.R. board holds the 5 I.R readers (couple) which control the 5 reading positions. It also contains the 2 I.R readers (couple) controlling the mechanics' movements. They detect the high and the low position when light passes the counter wheel aperture.



7.4 Mechanical Parts



The mechanical parts consist of the mechanical guide and the tube supports (one each for the upper and the lower end of the tubes).

The mechanical guide supports the motor, the gear, the carriage, the bearings, and the I. R. board. The mechanical guide is fixed with 2 screws, one in the bottom and one at the top. To dismantle the mechanical guide dismantle the LCD display first. Then take off the screws.

The I. R. board is fixed to the carriage by one screw. It is important to be fixed correctly to avoid movement of the tubes. To dismantle the I. R. board dismantle the mechanical guide.

Good alignment (through the specific hole in the mechanical guide) between the emitters and the receptors of mechanical sensor couple is necessary to have a clear pass of light.

The movement of the carriage is done by the motor, transmitted through the gear at the carriage and it's bearing. The motor has to put some pressure to the carriage to hold it and it's bearing (adjust approach motor by 2 screws).



PASS OF LIGHT IN MECHANIC SENSOR

Guide, carriage and bearing always have to be clean.

7.5 Test and Adjust the Instrument

- **I. R. SENSORS TEST:** With the instrument switched off (no tubes present), place a jumper in JP1 (main board). Then switch the instrument on and wait to the end of test. At the end of test the display shows the conditions of every position in the first line. Now insert one tube to any position. For that position a black square will appear (first line). If that tube is removed, the black square has to be disappear. Otherwise a problem has occurred.

Note: The tube must be filled with blood or some other non transparent medium.

- **TEMPERATURE SENSOR:** Following the procedure of I. R. Test (JP1) the temperature can be monitored in the 2 last digits of the second line of the display. To control that temperature the instrument has to be closed and switched on for at least 1 hour. If any adjustment is necessary, open the instrument adjust the trimmer, close the instrument and wait some minutes to check it.
- **MECHANIC TEST:** When the instrument is in "LOAD", put the jumper JP1. The reader starts moving and will send the quantity of steps of every movement ONLINE at the end of every movement (to printer and LCD) in hexadecimal format. In first position the steps of the LOW-UP movement and in second position the steps of UP-LOW movement are displayed. After some movements check if the variation between movements is OK. A variation greater than 10 steps is abnormal. Take off JP1 to stop the movements. During this test analysis can be run. If the reproducibility of that test is bad, the results might be erroneous. Check the conditions of the bearings. The step motor could be dusty or not adjusted.

If after some minutes of moving up or down the instrument does not detect the mechanical sensor, "!" will be displayed in the first line of the screen and the moving direction will be changed. This means that the instrument has some mechanical problem.

- **TEMPERATURE CONVERSION:** The standard setting of the instrument will not give results with temperature conversion. If temperature conversion is needed, place a jumper in JP3. Then the results are converted depending on the temperature (Manley table). This will be indicated by "*" prior to the "LOAD", and "TEST" display.

7.6 How the Instrument Works

When the instrument is switched on, the LCD display will be set up. Then the reader moves up and down to test the mechanic sensors. After arriving at the down position the JP1 set is checked (to go a IR TEST), followed by a check for the presence of any tube in the instrument. If a tube is detected the “EXTRACT” message will be displayed. Take off the tube. If the tube is not removed within two minutes the instrument will continue to “LOAD” status (send the header online).

If a new tube is detected in “LOAD” an UP-DOWN movement will be carried out and analysis will be started. First the reader controls if the filling levels. If the level is incorrect, the system will printout “Level Error”. After 12 minutes results will be printed out. With no other tube in work the reader will stop. If a tube is removed during working time, the instrument will display “Sample Error”.

The instrument detects new tubes only when it arrives at the low position. The results remain in the LCD until another tube is loaded in that position. A dot is displayed, when no tube could be detected in one position. If the instrument does not detect any tube in any position it shows the “LOAD” message. If the filling level of a tube is out of range of the reader’s movement, the instrument might not detect a tube in this position.

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