HumaCount 30^{TS} and 60^{TS}

| Service Manual

CE

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Human

Diagnostics Worldwide

REVISION LIST OF THE MANUAL

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SYSTEM VERSION

HumaCount 60^{TS} and HumaCount 30^{TS}with software version 1.2 .

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SERVICE UND SUPPORT

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1 SAFETY INSTRUCTIONS

1.1 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 damage or personal injury, 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.

1.2 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 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 reported to the freight carrier for settlement or claim. 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 reported to the freight carrier for settlement or claim.

1.3 Intended Use of the Instrument

[IVD]

The instrument is intended for in vitro diagnostic application by professional users. It 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.

HumaCount 30^{TS} / HumaCount 60^{TS} hematology analyzers are fully automated cell counters for in vitro diagnostic use. The compact instruments were developed for small clinics, point-of-cares, and hospitals.

HumaCount 30^{TS} can process 30, HumaCount 60^{TS} can process 60 samples per hour and they are intended to determine the following 18 hematology parameters from a 25µL whole blood sample:

- WBC - LYM - MON - GRA - LYM% - MON% - GRA% (three-part WBC differential)
- HGB - RBC - HCT - MCV - RDW - MCH - MCHC
- PLT - MPV - PCT – PDW

1.4 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.

1.5 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 off according to the regulations for the disposal of electronic components.
Batteries, power packs and similar power source have to be dismounted from electric/electronic parts and disposed off in accordance with applicable local regulations.

1.6 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.
Decontamination should be performed by authorised well-trained personnel only, observing all necessary safety precautions. Instruments to be returned have to be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination 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.

1.7 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 labeled instruments with the „BIOHAZARD" warning label below.

FIGURE 1
Biological Hazard Symbol

Notes:

2 INTRODUCTION

Since HumaCount 30^{TS} and HumaCount 60^{TS} have so much common characteristics, we issue a common Service Manual covering both instruments. Information herein applies for all instruments unless otherwise noted.

To be well up in the instruments, please read this manual carefully to have the knowledge for servicing the instruments perfectly and avoid extra costs and wasting precious time.

In this manual, we are using the following conventions:

HC30TS – stands for HumaCount 30^{TS}

HC60TS – stands for HumaCount 60^{TS}

This HumaCount 30^{TS} / HumaCount 60^{TS} Service Manual contains the functional descriptions of all analyzers, operation of the fluidic systems, adjustments and settings, and very important information for the service personnel about the service operations and possible problems.

2.1 Name and serial number

Name:	HumaCount 30^{TS} / HumaCount 60^{TS} Hematology Analyzer
Serial No.:	Every instrument has its own serial number, which is printed on the rear panel label and it can be read out from Device Information or from the self test submenu. This identity number is write-protected by HUMAN.

2.2 Integrated software

The integrated software controls the instrument operations, displays, stores, recalls data, and allows the user to perform QC and calibration procedures and modify the user settings. The software version number can be read out from the Device Information or from the Self test submenu.

Every HC30TS / HC60TS software version is upgradeable (using an USB flash drive) by the latest program developed by HUMAN, and it can be downloaded from: http://www.human.de

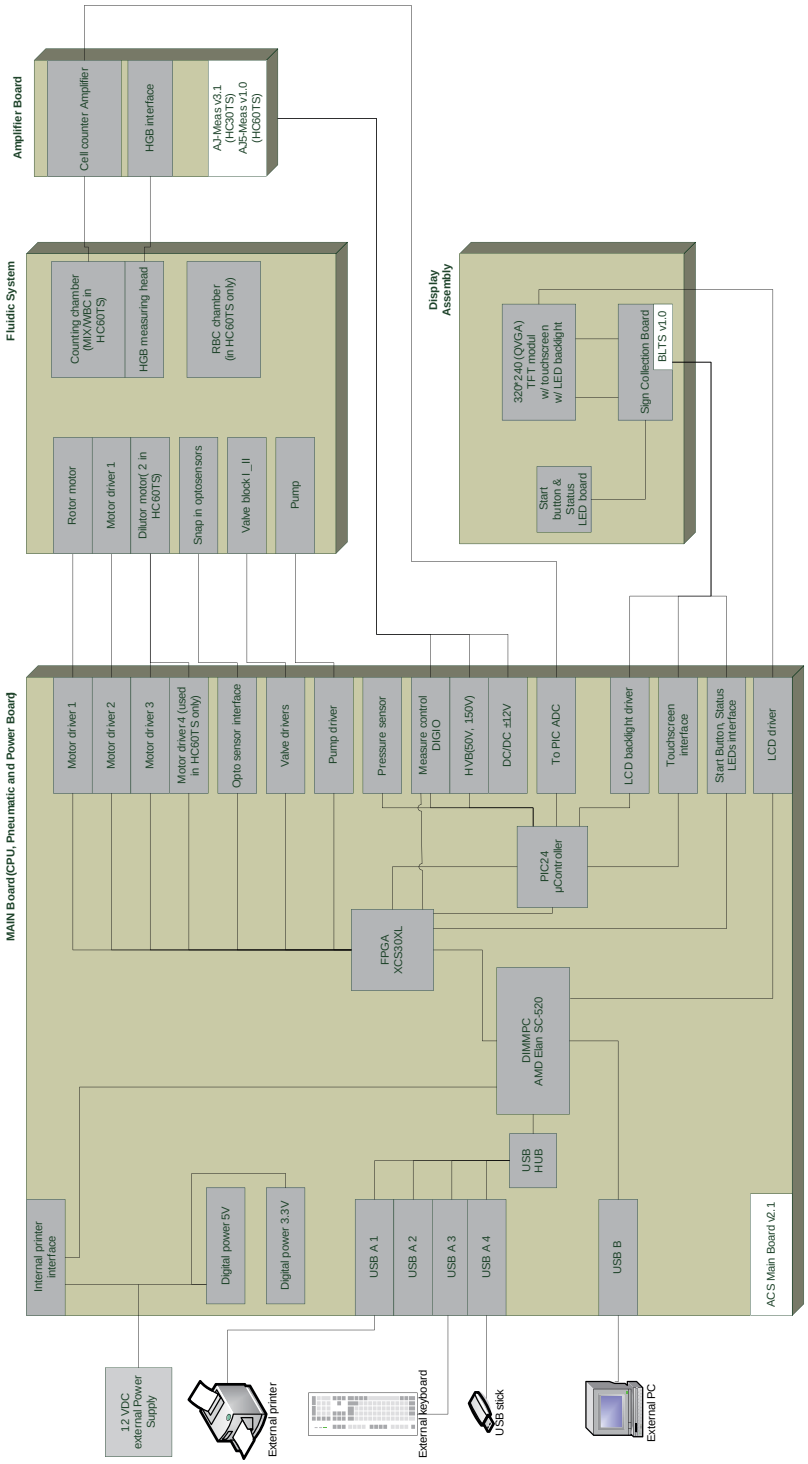
3 FUNCTIONAL DESCRIPTION

3.1 Main electronic parts of the analyzers

HC30^{TS} / HC60^{TS} contain the following electronic parts:

1. Counting chamber (2 pcs in HC60TS) with electrodes and measuring aperture
2. HGB Measuring Head
3. Cell Counter Amplifier Board
4. MAIN CPU Board with Dimm-PC and measurement processing unit, 4 motor controllers, valve & pneumatic controller/driver, pump driver and power supply for internal printer (+7.5V) and digital circuitry (+5V, +3.3V)
5. DIMM-PC module
6. Motors with opto-boards of needle moving motor (H) and sample rotor/needle moving motor (V)
7. Dilutor block with opto-board for sampling, diluent, lyse and cleaner
8. Valve boards (set of 5 and max. 7)
9. Peristaltic Pump (2 pcs in HC60TS)
10. USB interface
11. Graphic LCD Display Module with touch-screen
12. Start Button Panel
13. Internal Printer

FIGURE 2
Block diagram



3.1.1 COUNTING CHAMBER WITH ELECTRODES AND MEASURING APERTURE

Impedance method is used for determination of volume and number of cells. In this method a known volume of dilution is drawn through a small aperture. Constant current is passed through the aperture from one side to the other. When a cell passes through the aperture, it causes a change in resistance, which generates a voltage pulse.

The amplitude of the voltage pulse is proportional to the ratio of cell volume per aperture volume. This is used to determine the volume of cells. The number of cells can be obtained by counting the pulses. In the HC30^{TS} there is one cell-counter probe: the aperture size is 70 µm and has a reference electrode assembly and U-shaped metal fixing as it is shown in the figure below.

The aperture is made of ruby and it is molded into the end of the measuring tube. In the HC60^{TS} there are two separate chambers: one for counting RBC with an aperture of 80 µm, and another for MIX/WBC/HGB with 100 µm aperture.

FIGURE 3
Measuring chamber

1 **Washing inlet**
2 **Counting chamber**
3 **Opening for measuring tube**
4 **Chamber extender**
5 **Platinum electrode**
6 **Draining connection**

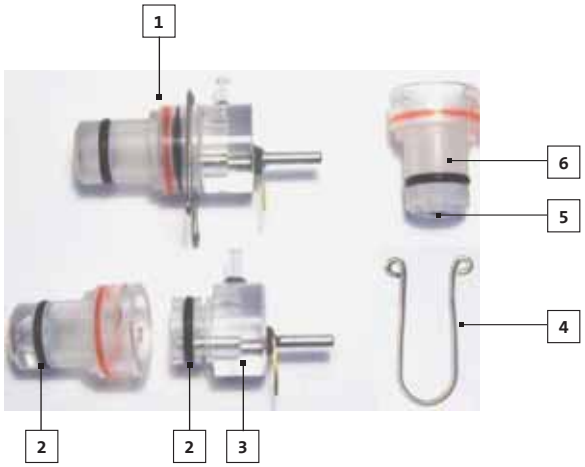


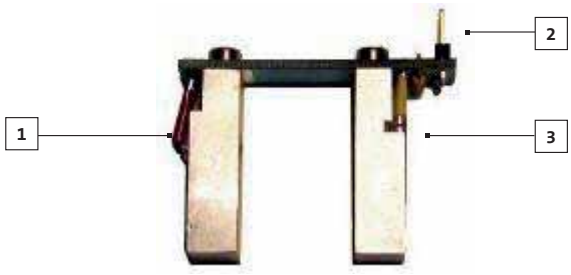
FIGURE 4
Measuring tube

1 **Complete measuring tube**
2 **O-rings**
3 **Reference electrode**
4 **U-shaped metal fixing**
5 **Aperture**
6 **Measuring tube with aperture (70/80/100µm)**

3.1.2 HGB MEASURING HEAD

Hemoglobin head is placed around one measuring chamber in all instruments. It contains: light source (LED) at 540 nm wavelength and Photo Detector (TSL235). The Photo Detector converts the light to frequency. The HGB concentration is a logarithmic function of this frequency measured by the FPGA circuit of the MAIN board.

FIGURE 5
HGB measuring head



1 LED
2 Connection to the amplifier
3 TSL 235

The analyzer performs enhanced hemoglobin measurement technology for HGB measurement. The frequency output signal of TSL235 is counted by a digital counter in the FPGA circuit.
This counter counts up while the LED is on and counts down while the LED is off. The LED and direction of counting are switched with a 100 Hz signal. This method provides “real time backlight correction”, which makes the HGB measurement more precise in changing backlight environment situation as well.
There are two kinds of HGB measurement:

- Sample measurement (before RBC counting)
- Diluent/blank measurement (in WBC washing phase)

The HGB result is calculated from these measurements by:

$HGB \cong \log (CNT_{diluent\ light} / CNT_{sample\ light})$

! Due to enhanced HGB technology, HC30TS / HC60TS is less sensitive to incident light changes. However, it is recommended to keep side door closed during measurements.

3.1.3 CELL COUNTER AMPLIFIER BOARD – HC30TS

Amplifier board includes its own voltage regulator, connection interfaces to HGB head and to MAIN board. There is a current generator circuit on it, which works from 50V measuring voltage (generated by MAIN) and the probe voltage (DC) is amplified with a voltage follower (output: ELV). Nominal measuring current is 870 µA.
Amplifier board includes one input connector for the chamber (measuring electrode). There are two opto switches (U1, U3) to connect high voltage to the probe with HSW signal and isolate the input of the amplifier. Test circuit makes possible to generate test pulses (with TEST and PLS signals through FETs) for checking the proper operation of the amplifier channel.

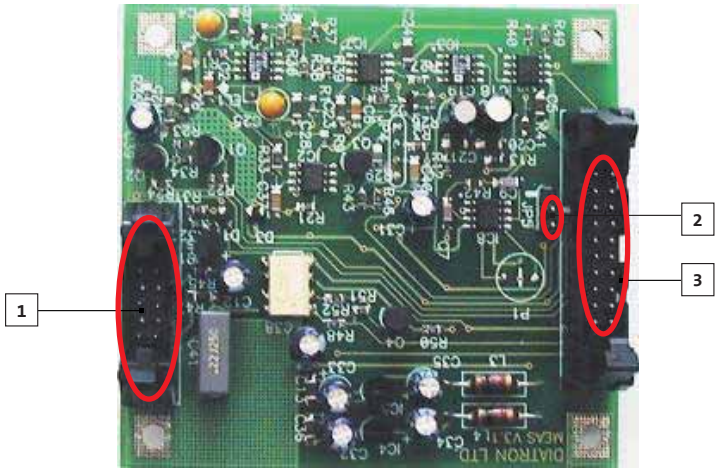


FIGURE 6
Cell counter amplifier board

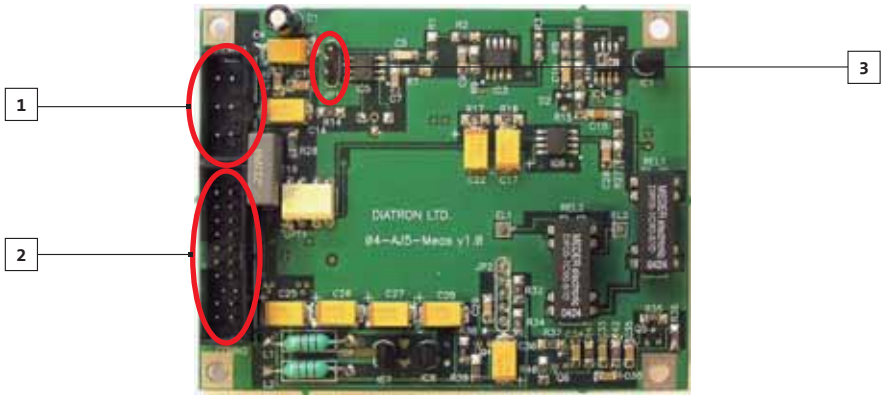
1 **Connection to HVB on Main**
2 **Connection to CSA1 on Main**
3 **Connection to DIGIO on Main**

Amplifier board includes a 3-stage main amplifier channel, which gains input signal to the 0...3.3 V range (this is the input range of the A/D converter, which is placed on the MAIN board). The RSW signal changes the gain (RBC, WBC) in the feedback of the second amplifier stage with U2 (MAX319) analog switch. Amplifier gain and offset are adjusted by software.
DHON signal switches on the LED and the MVON signal – which is active during counting – switches off the Photo Detector in the HGB head, to prevent noise generated by the HGB detector.
The other side of the amplifier board contains special connectors for the chamber and the HGB head (JP4).

3.1.4 CELL COUNTER AMPLIFIER BOARD – HC60TS

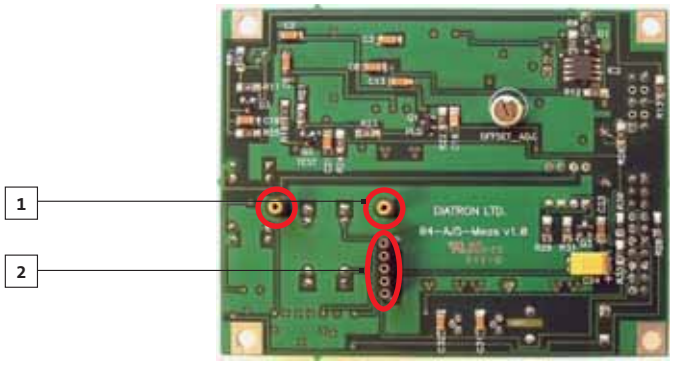
Amplifier board includes its own voltage regulators, connection interfaces to HGB head, to chamber electrodes, high voltage and DIGIO connector to Main board. There is a current generator circuit on this board, which works from 50V measuring voltage (generated by the High Voltage Circuit on Main board) and the probe voltage (DC) is amplified with a voltage follower (output: ELV). Nominal measuring current is 870 µA.
Amplifier board includes one input connector for each measuring chamber (measuring electrodes). There is one opto switch (OPT1) and a relay (REL1) to connect high voltage to one of the probes with HSW signal and to isolate the input of the amplifier. Test circuit allows generating test pulses (with TEST and PLS signals through Q1, Q2 FETs) for checking proper operation of each amplifier channel.

FIGURE 7
Cell counter amplifier board - front side



1 **Connection to Main board, HVB**
2 **Connection to Main board, DIGIO**
3 **Connection to Main board, amplifier in**

FIGURE 8
Cell counter amplifier board - back side



1 **Connection to the electrodes**
2 **Connection to HGB head**

Amplifier board includes a 3-stage main amplifier channel, which gains input signal to the 0...3.3 V range (this is the input range of the A/D converter on the Main board). The RSW signal (with Q8 transistor) changes the input electrode through REL2 relay.

The bottom side of the amplifier board contains special connectors for the electrodes and the HGB head (JP2).

DHON signal - from the MAIN board - switches on (with Q4) the LED and the PLS signal switches off the Photo Detector in the HGB head, to prevent noise generated by the HGB detector.

3.1.5 MAIN CPU BOARD

This board contains:

- DIMM-PC and measurement processing unit,
- 4 motor controllers,
- valve & pneumatic controller/drivers, pump driver(s)
- power supply for internal printer (+7.5V) and digital circuitry (+5V, +3.3V)

MAIN board is responsible to control the instrument: contains the main power regulator circuits, valve and motor driver circuits and other connections for the fluidic and pneumatic system's parts, responsible for the specific measurement processing functions.

The central micro-controller with a FPGA and with several other digital chips (buffers, decoder, multiplexer) handles the pneumatic system, displaying, measurement and data management.

Power system: filtering the +12V Input and generates +3.3V (FPGA), +5V (Digital power), +7.5V (Printer power). Filtered +12V is used for the power of motors and valves.

Motor drivers: 4 power drivers; Horizontal, Vertical/Sample rotor motors and dilutor motors (2 in HC60TS) have separated ribbon cable connections.

Valve driver: consists two 8-bit, powered output shift registers (with built in protection diodes) and there is one common ribbon cable connection for the valve boards. The peristaltic pump has a separated power FET driver circuit for more reliable operation.

Measurement processing: the A/D conversion made by the micro-controller itself, but several preprocessing steps (time limits, noise handling, pulse integration) taken by the external analog circuitry.

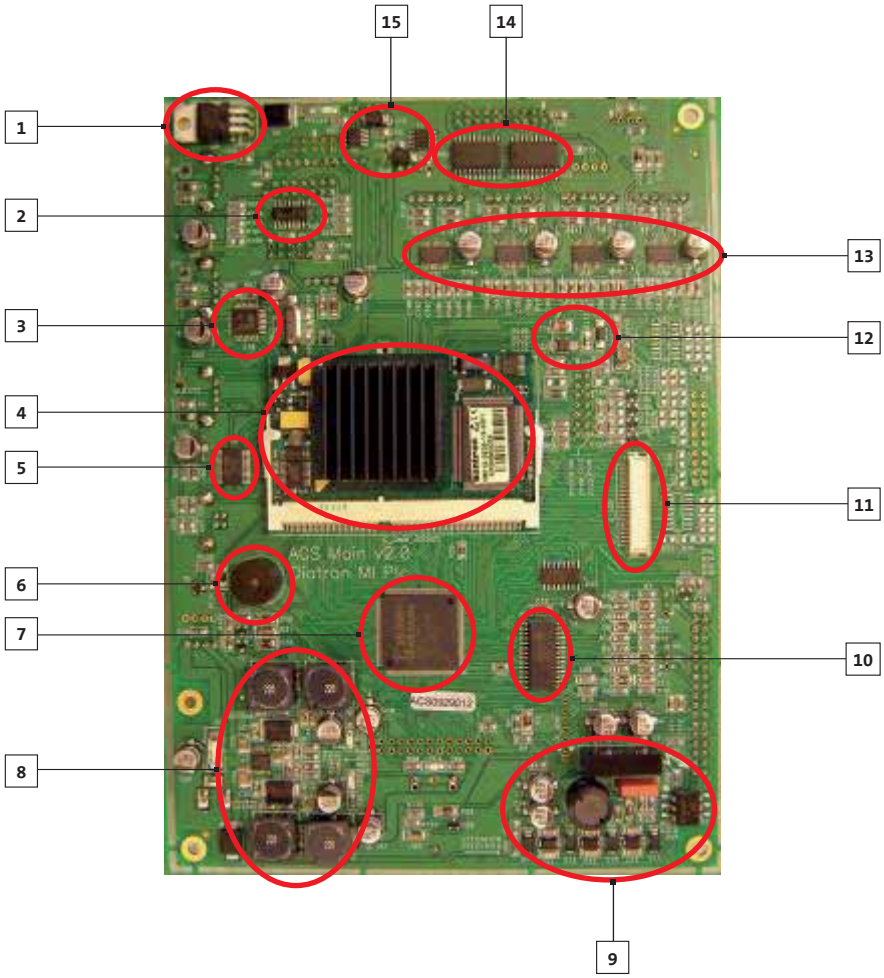


FIGURE 9

Main board - front view

1 **Power Supply for internal printer 7.5 VDC**
2 **Opto detectors` shift register**
3 **USB HUB**
4 **DIMMPC**
5 **RS232/USB Converter**
6 **Speaker**
7 **FPGA**
8 **Power Supply 12VDC->5VDC, 3.3VDC**
9 **High Voltage Circuit 12VDC -> ±12VDC, 50VDC for measurement, 150VDC for cleaning**
10 **Microcontroller**
11 **TFT connection**
12 **TFT backlight driver**
13 **Motor drivers**
14 **Valve drivers**
15 **Pump drivers**

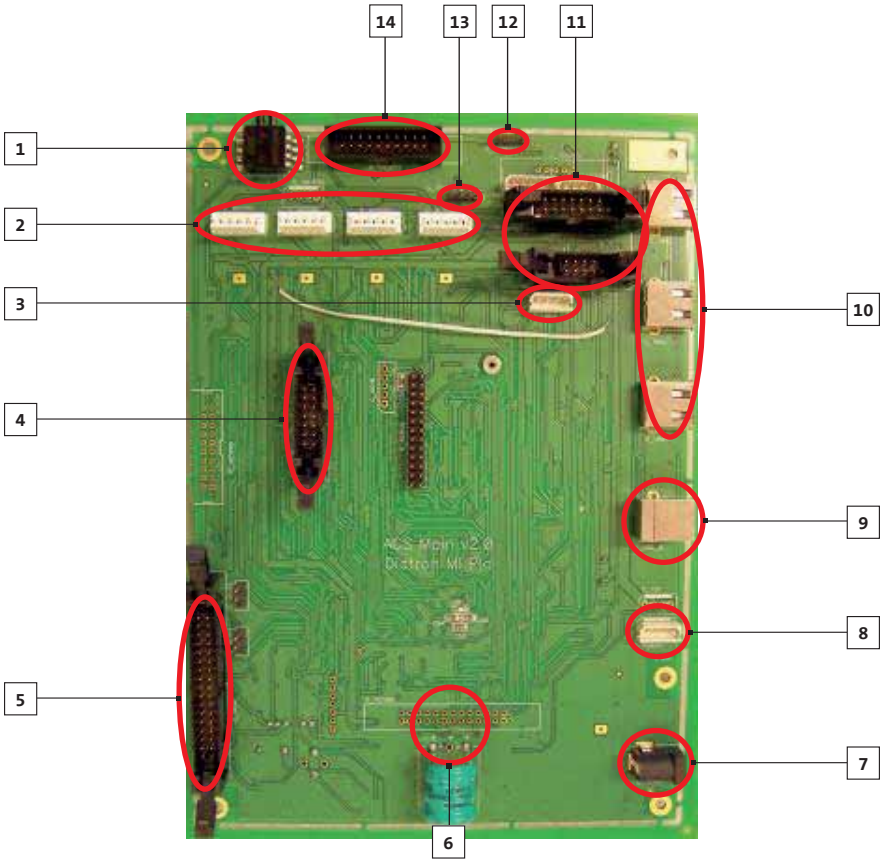


FIGURE 10

Main board - rear view

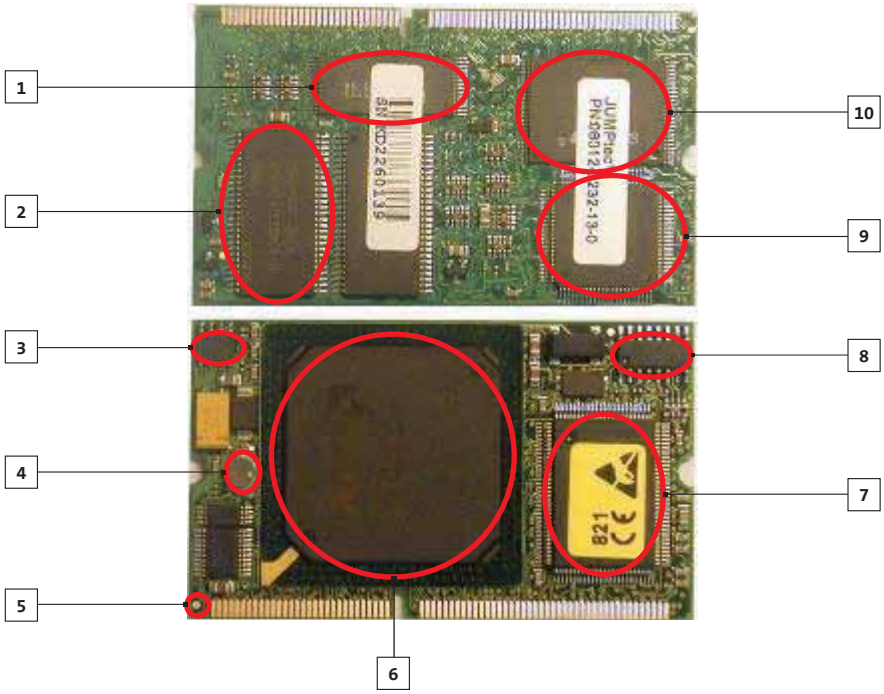
1 **Pressure Sensor**
2 **Motor Connectors**
3 **Front Panel USB Connector**
4 **Connector to TFT, Backlight and Start Button**
5 **Connectors to Amplifiers**
6 **Internal battery**
7 **Power Connector**
8 **Power Switch Connector**
9 **USB B Type Interface**
10 **USB A Type Interfaces**
11 **Connectors to Optos**
12 **Pump Connector #1**
13 **Pump Connector #2 (HC60TS Only)**
14 **Valves Connector**

3.1.6 DIMM-PC* MODULE

The MAIN board incorporates a credit-card sized PC, named Dimm-PC*. The processor on the Dimm-PC is a 133MHz Pentium-class core, with 32Mbytes on-board RAM, and 32Mbytes on-board flash. This is the SSD (Solid State Disk) of the analyzer, so instrument software with all user settings, calibration, database, etc. is stored on the Dimm-PC.

** DimmPC® is the Trade Mark of Kontron Embedded Modules GmbH*

FIGURE 11
DIMM-PC

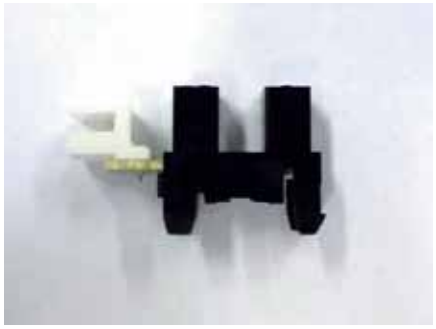


1 **Flash BIOS**
2 **32 Mbytes RAM**
3 **CMOS EEPROM**
4 **On-board SMPS**
5 **Edge connector**
6 **AMD Elan SC520 CPU**
7 **Super I/O**
8 **Realtime clock**
9 **SSD controller**
10 **SSD**

3.1.7 OPTO SENSORS

Opto sensor snap-in modules are responsible for checking motor positions. There are 6 opto sensors in HC60TS, and 5 in HC30TS (see cabling diagram).

FIGURE 12
Opto sensor



3.1.8 VALVE BOARDS

There are two kinds of valve boards: Valve board 1-5 and Valve board 6-12.

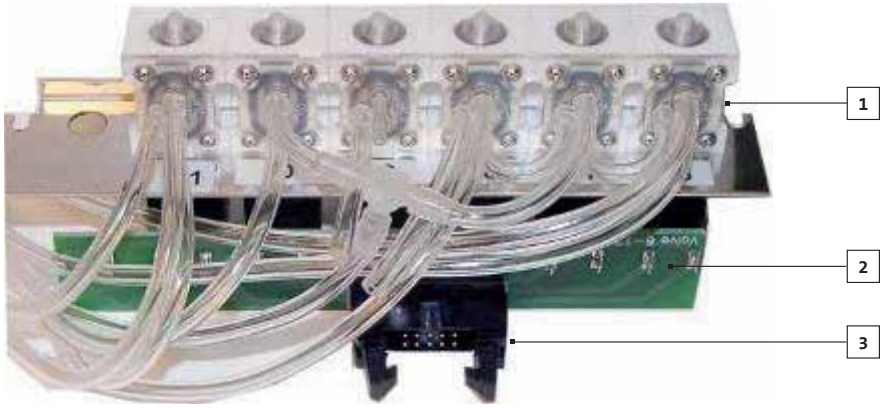


FIGURE 13
Valve assembly

1 **Valves**
2 **Valve Board**
3 **Connection to Main board**

HC30TS has 5 valves, while HC60TS has 6 valves in Valve board 6-12 module. The valve boards are connected to controller and driver chips which are located on the MAIN board.

3.1.9 TFT DISPLAY AND START BUTTON BOARD

FIGURE 14
Front panel connections

1 **Touchscreen connector**
2 **Start button & status LED connector**
3 **Ribbon cable from TFT/ Touch board to Main board**
4 **TFT connector to Main board**
5 **TFT Backlight connector**
6 **Ribbon cable from TFT/ Touch board to Main board**

3.1.10 EXTERNAL POWER SUPPLY

The analyzer works with an external power supply. The figure below shows the power supply unit generating 12VDC.

The power supply modules have an auto range input, which makes possible to use them with 230V or 115V mains outlet and it has the CE and UL safety certificate. The input socket of the power supply is a standard 3-terminal plug, with power cable connection; the output is a coaxial power connector.

FIGURE 15
Power supply

1 230 AC inlet
2 12V DC outlet

4 MAIN MECHANIC AND FLUIDIC PARTS

HC30TS and HC60TS Hematology Analyzers consist of the following mechanic and fluidic parts:

1. Sample rotor
2. Sampling needle
3. Washing head
4. Sample/Horizontal moving unit
5. Micro Dilutor
6. Dilutor
7. Chamber
8. Cell-counter probe
9. Puffer reservoir
10. Pump
11. Valves
12. Tubing

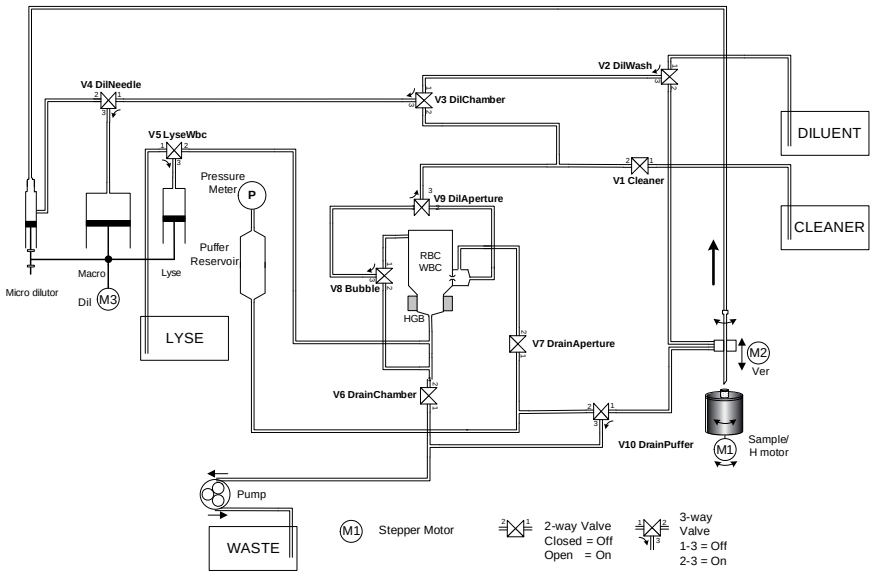
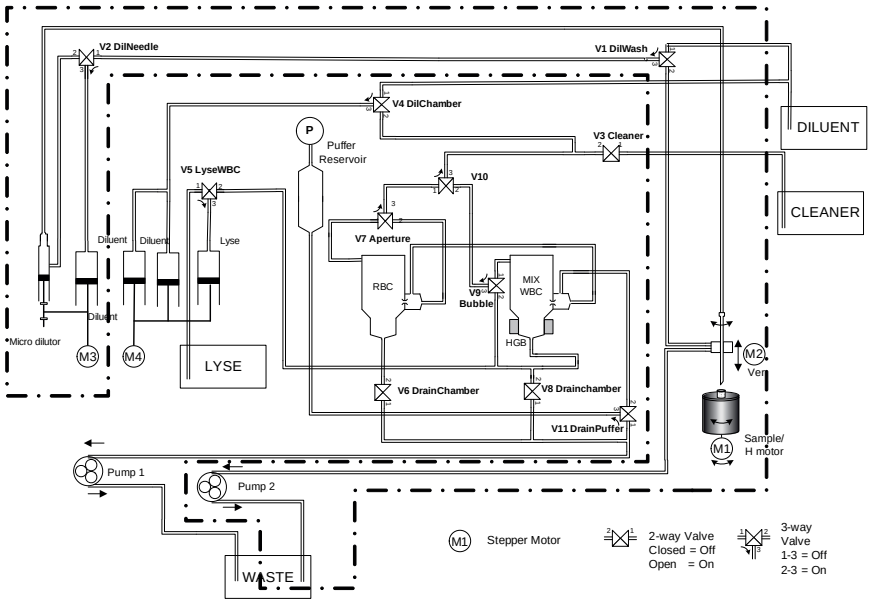


FIGURE 16 :
HC 30TS fluidic schematic

FIGURE 17

HC 60TS fluidic schematic



4.1 Single parts

4.1.1 SAMPLE/HORIZONTAL AND VERTICAL MOTORS

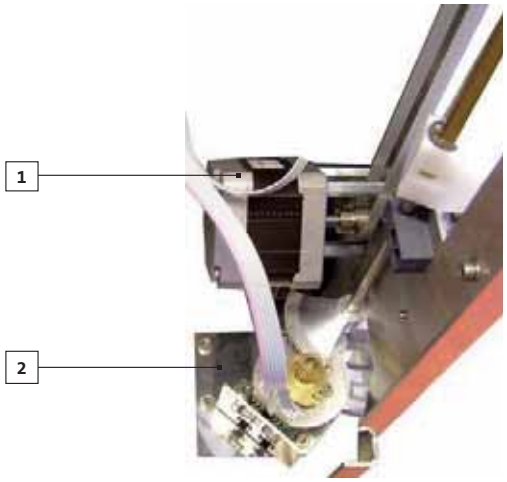
! Sample rotor is maintenance-free.

HC30TS and HC60TS Hematology Analyzers has a sample rotor for safety and more precise sample handling. Commonly used sample tubes are supported by replaceable tube adapters.

The Sample rotor unit uses a stepper motor, connected to the MAIN board directly. The rotor has opto sensors for positioning.

FIGURE 18

Sample probe motors



1 Vertical motor

2 Sample/Horizontal motor (not visible)

4.1.2 SAMPLING NEEDLE

Sampling needle is assembled in the H&V moving unit and it makes the sample aspirations. Correct setting of sampling needle is necessary and very important (see Chapter Adjustments).

4.1.3 NEEDLE WASHING HEAD

Washing head is located at the bottom of the H&V moving unit and it is for cleaning the outer surface of the sampling needle. This washing process is made with diluent reagent and the fluid is drained by the pump. The arrows on the picture show the direction of diluent flow during sampling needle washing.

! Clean or replace washing head yearly, or after 10 000 measurements.

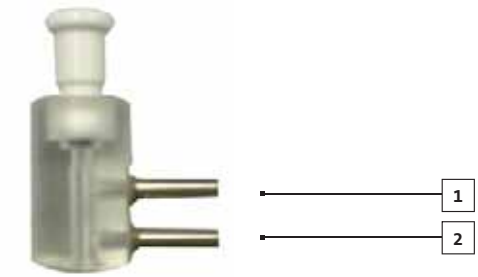


FIGURE 19
Needle washing head

1 Clean diluent
2 Pump to waste

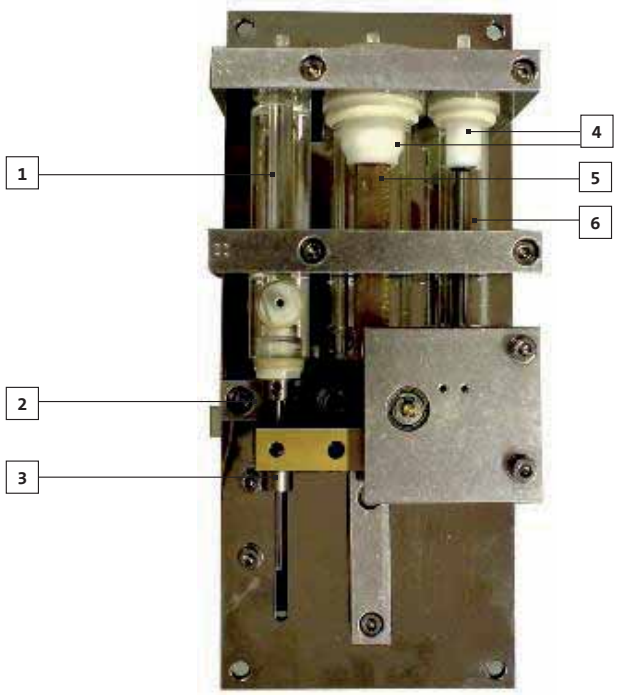
4.1.4 PUFFER RESERVOIR

The glass puffer reservoir is directly connected to the pressure sensor.
During measurement, there is no pump activity, so the puffer reservoir maintains measuring vacuum stable.
The instrument measures relative pressure so measuring vacuum is independent of atmospheric pressure.

FIGURE 20
Puffer reservoir

4.1.5 DILUTOR BLOCK – HC30TS

FIGURE 21



1 Micro dilutor
2 Positioners
3 Positioners
4 Pistons
5 Pistons
6 Diluent syringe
7 Lyse syringe

In HC30TS this unit includes one dilutor stepper motor. The Micro dilutor syringe makes the aspirating while the motor moves down. The syringes are mechanically connected with a loose mechanism, so there is a phase along the track, where the micro dilutor doesn't move.

! Maintenance should be provided to the piston tips, by applying neutral silicon grease to the cogged end of the Macro and Lyse pistons, between the syringe and the tip itself. This will ensure optimum sealing and longer lifetime of piston tips. Greasing of the cogged transmission parts (cogwheel and cogged bar) should be done regularly using machine grease. It is recommended to check and repeat greasing of piston tips, and transmission gear every year, or after 10000 measurements.

4.1.6 DILUTOR BLOCK – HC60TS

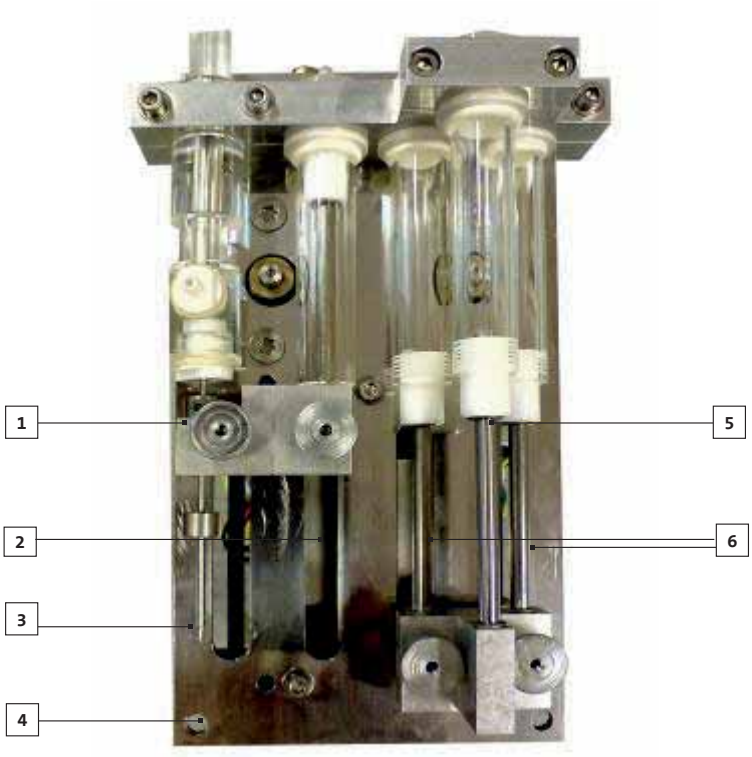


FIGURE 22

1 **Micro dilutor**
2 **Diluent 1 syringe**
3 **Positioners**
4 **Positioners**
5 **Lyse syringe**
6 **Diluent 2 syringes**

In HC60TS this unit includes two dilutor channels – one for diluent and sampling, and another one for lyse and diluent reagents. There are two stepper motors, 4 opto sensors, five syringes and piston rods with gear transmission. The Micro dilutor syringe makes the aspirating while the motor moves down. The syringes are mechanically connected with a loose mechanism, so there is a phase along the track, where the micro dilutor doesn't move.

4.1.7 MEASURING BLOCK (HC30TS)

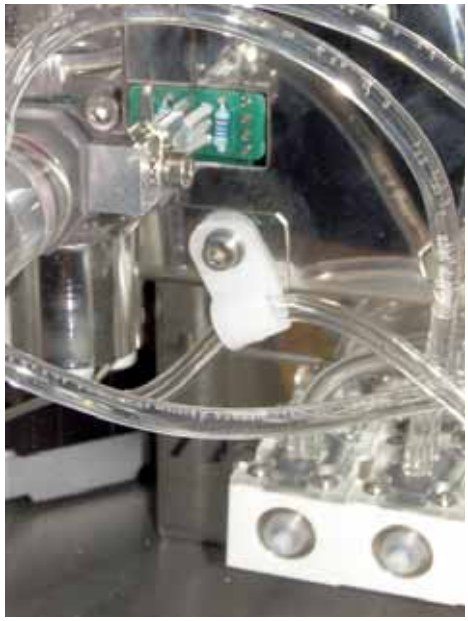
The measuring block contains all components, counting chamber, measuring tubes, HGB head, draining tubes.

FIGURE 23

4.1.8 MEASURING BLOCK (HC60TS)

The measuring block contains all components, counting chambers, measuring tubes, HGB head, draining tubes.

FIGURE 24



4.1.9 PUMP

Pump generates regulated vacuum and drains the fluidic system. It is connected to the MAIN board and it has its own driver circuit (Power FET). In HC60TS there are two pumps.
The pump is maintenance free.

FIGURE 25

4.2 Assembled Analyzer

4.2.1 FRONT PANEL

FIGURE 26

1 TFT display
2 Start button
3 USB socket
4 Sample holder/Sample rotor

4.2.2 SIDE PANEL

FIGURE 27

1 Cover screws
2 Cover screws

4.2.3 REAR PANEL (HC30TS)

FIGURE 28

1 Cover screw
2 Reagent inlets
3 cover screw
4 Power switch
5 Cover screw
6 USB A inlet
7 USB B inlet
8 Cover Screw
9 Grounding screw
10 12 VDC power IN
11 Cover screw

4.2.4 CONSTRUCTION FRONT

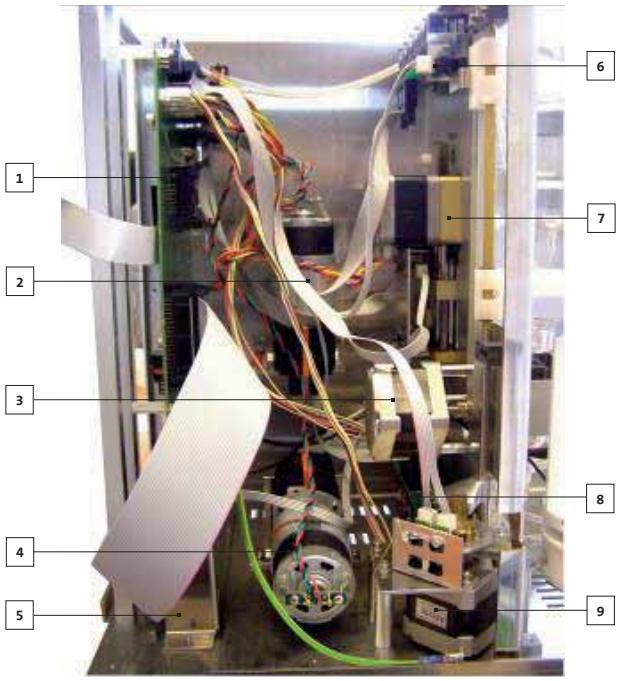


FIGURE 29

1 Main board
2 Pump II (only in HC60TS)
3 Vertical motor
4 Pump I
5 Amplifier box
6 Valves
7 Dilutor motor
8 Valves
9 Sample/Horizontal motor

4.2.5 CONSTRUCTION SIDE

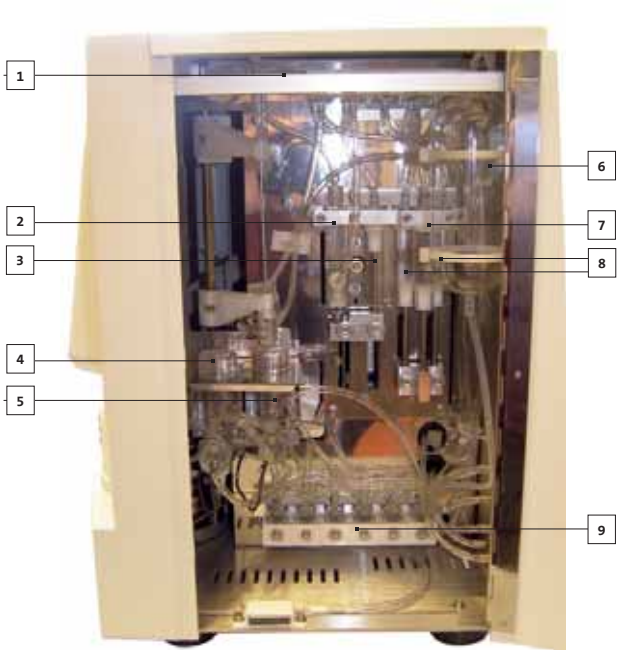


FIGURE 30

1 Valves 1-5
2 Micro dilutor
3 Dilutor 1
4 RBC Chamber
5 MIX/WBC Chamber (only in HC60TS)
6 Puffer reservoir
7 Lyse syrenge
8 Dilutor 2
9 Valves 6-10 (6-11 in HC60TS)

FIGURE 31
Construction side of HC30TS

1 MAIN board
2 Dimm-PC

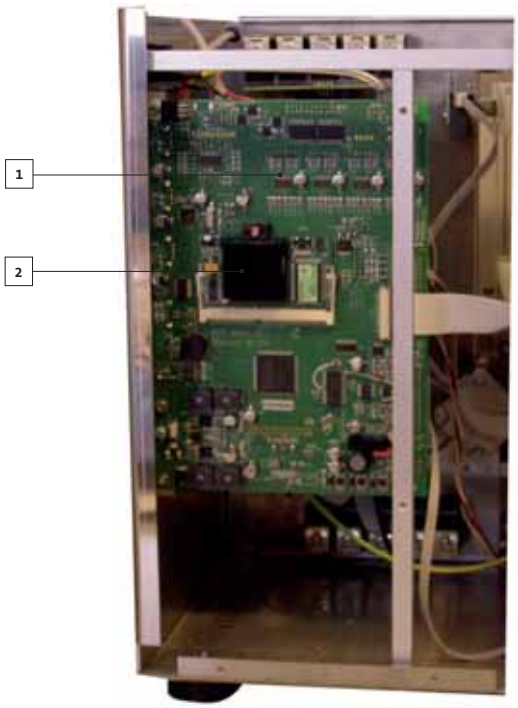
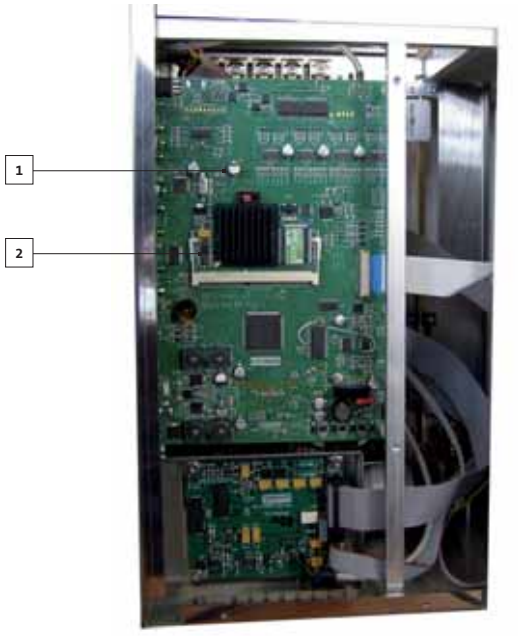


FIGURE 32
Construction side of HC60TS

1 MAIN board
2 Dimm-PC



5 OPERATION OF THE FLUIDIC SYSTEM

This section describes the main fluidic steps of HC30TS / HC60 TS measurement cycle. The instrument's Fluidic Schematics are shown in Section 10.4 of this manual. The following figures show total measurement flow diagram and detailed descriptions of processes for understanding the fluidic system work.
The following steps are introduced in this section:

1. Flow diagram of measurement
2. Initialization process
3. Sampling process
4. Needle washing process
5. Diluting process
6. Lysing process
7. Counting process
8. Chamber draining process
9. Shutdown process

In the detailed process description figures, the active tube is filled with black color, while an arrow shows the direction of the flow. Moving mechanic parts have another arrow indicating direction of movement. Only opened (On) valves are mentioned in this section while all the other valves are closed (Off).
HC30TS / HC60TS employs software counters to estimate waste (and other reagent) level. Software integrates volume of the reagents used, and gives a message when this volume reaches the preset tank capacity.

5.1 Initialization of the Fluidic System

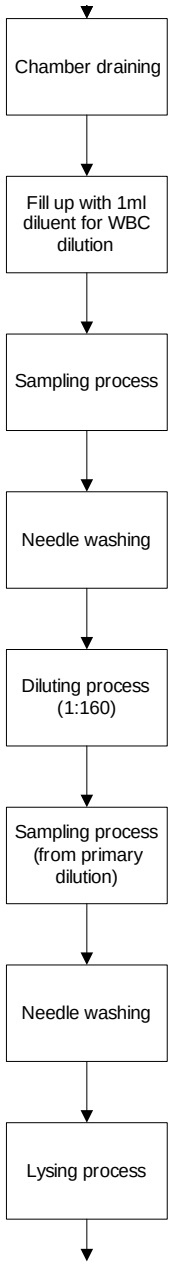
Fluidic initialization process performs the following steps:

- Checking of pump and pressure sensor by generating measuring vacuum
- Positioning all mechanical components by scanning moving range (with end-switches)
- Priming of reagents
- Cleaning of tubing & measuring chamber
- Cleaning of aperture with high-pressure back-flush, cleaner reagent & high-voltage burning

5.2 Operation of the fluidic system in HUMACOUNT 30 TS

5.2.1 FLOW DIAGRAM OF MEASUREMENT

FIGURE 33



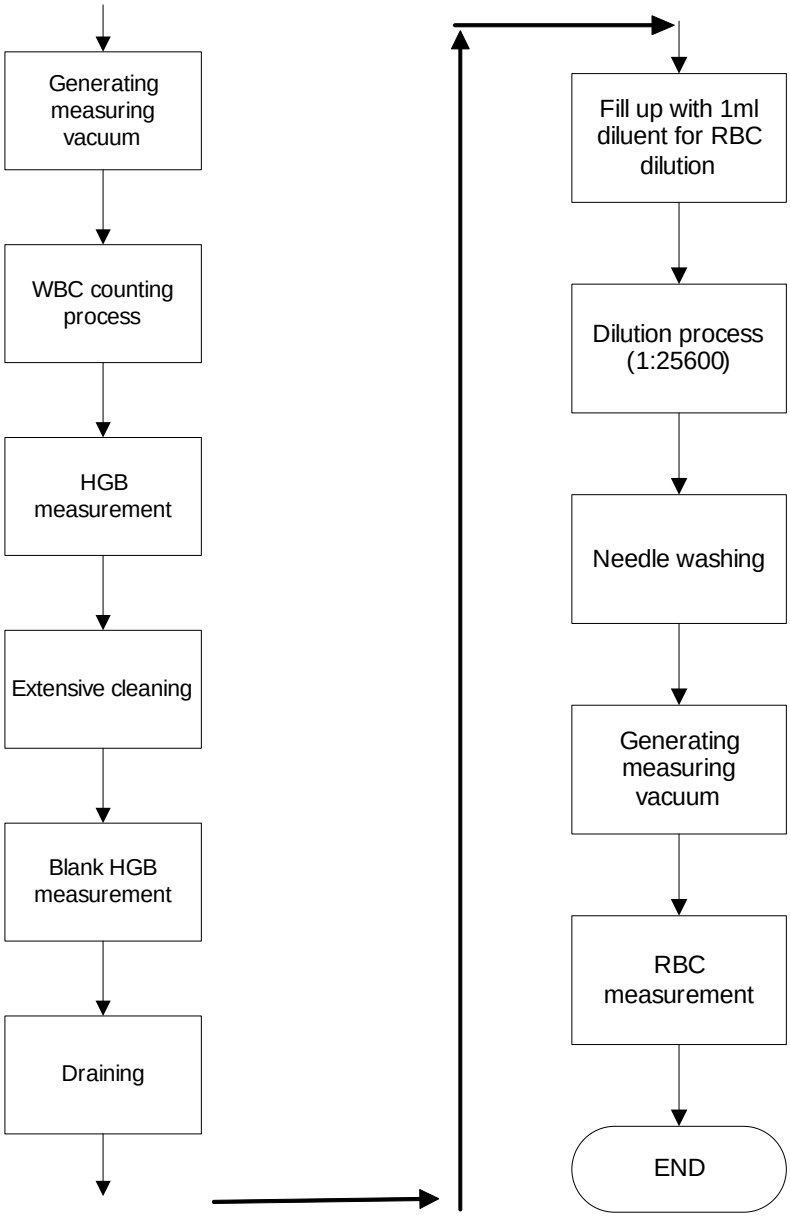
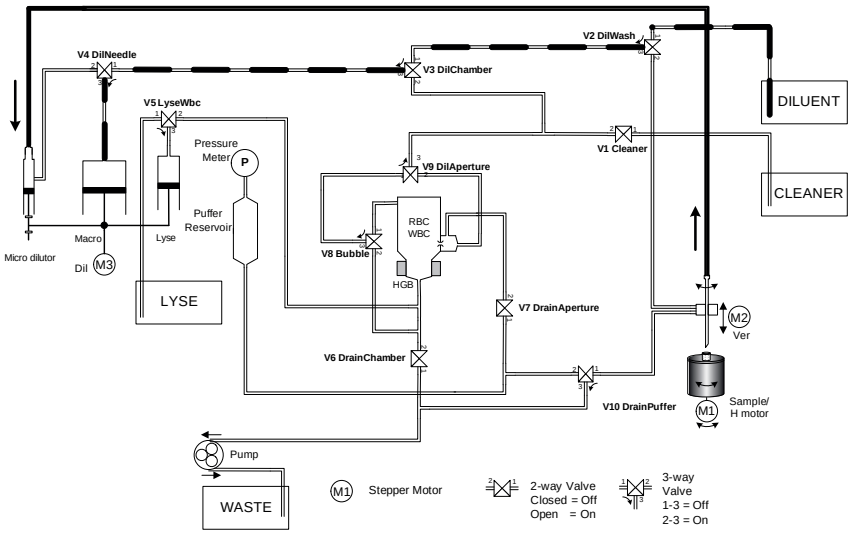

Generating measuring vacuum
WBC counting process
HGB measurement
Extensive cleaning
Blank HGB measurement
Draining
Fill up with 1ml diluent for RBC dilution
Dilution process (1:25600)
Needle washing
Generating measuring vacuum
RBC measurement
END

FIGURE 34

5.2.2 SAMPLING PROCESS

The aspirating needle aspirates 25 µL (50 µL in prediluted mode) of blood sample. The Micro dilutor syringe makes the aspirating while the M3 Micro-dilutor motor moves down. The syringes are mechanically connected with a loose mechanism, so there is a phase along the track, where the micro dilutor doesn't move.

FIGURE 35



There is also another sampling process for the second (RBC) dilution, 25 µL of primary dilution is aspirated by the sampling needle from the chamber but it is kept in the sampling needle during the WBC measurement and the cleaning process.

5.2.3 NEEDLE WASHING PROCESS

Both instruments clean the sampling needle with diluent in the washing head after sampling. It is important to clean the outer surface of the sampling needle to avoid inaccurate sampling.

The Macro syringe doses and the pump drains the diluent from the washing head, while sampling needle moves upwards so that the total length of it is washed and cleaned. This process is called total sampling needle washing, and it is mainly used after taking primary sample from sample tube.

Another process, which is washing only a smaller part of the sampling needle, is the same but the needle does not move in the total length. Some procedures perform this kind of sampling needle washing.

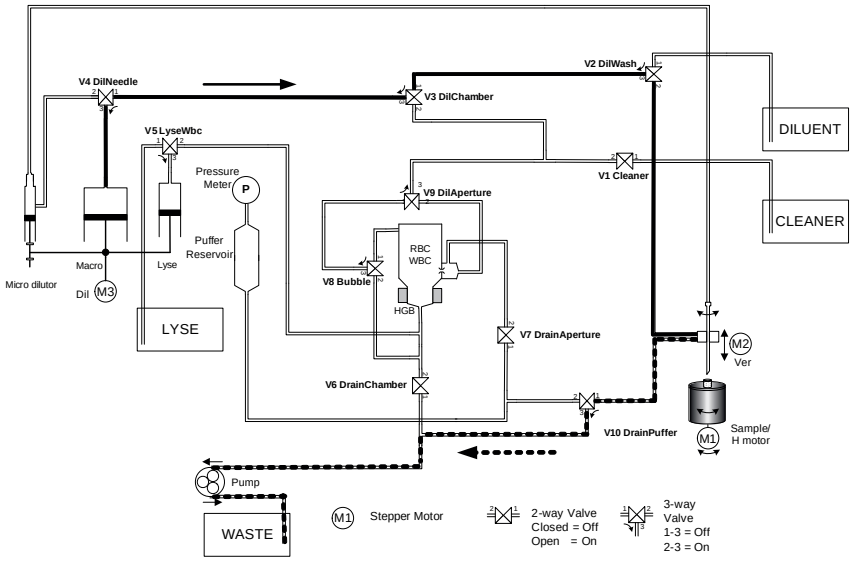


FIGURE 36

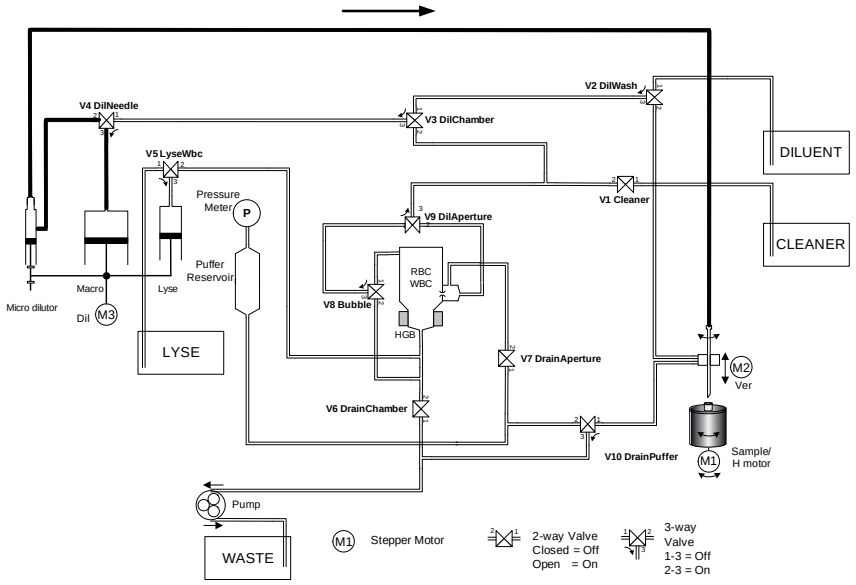
The Macro syringe pushes the diluent through V4 (Off), V3 (Off), V2 (On). The Pump aspirates the diluent from the washing head through V10(On), while the M2 Vertical motor moves the sampling needle up.

5.2.4 DILUTING PROCESS

The parts of the fluidics are rinsed with diluent reagent. The measuring chamber is filled up with 1 ml of diluent. This method prevents the chamber from dirt and makes the diluting process faster.

The sampling process has aspirated 25 µL of sample, which is in the sampling needle. In the first diluting step the sample is dispensed into the measuring chamber with 3 ml of diluent, which comes from the Macro syringe through V4 (On) and Micro-dilutor, while the M3 Dilutor motor moves upwards. This process makes the 1:160 first dilution rate in the chamber.

FIGURE 37



The second sample – 25 µL of primary dilution – is stored in the sampling needle during the WBC measurement and the cleaning process. The instrument makes the second (RBC) dilution into the chamber after these processes.

5.2.5 LYSING PROCESS

In this step the set lysing reagent is added into the measuring chamber through V5 (On), while the Lyse syringe moves upwards. This process makes the WBC/ HGB dilution with lyse reagent.

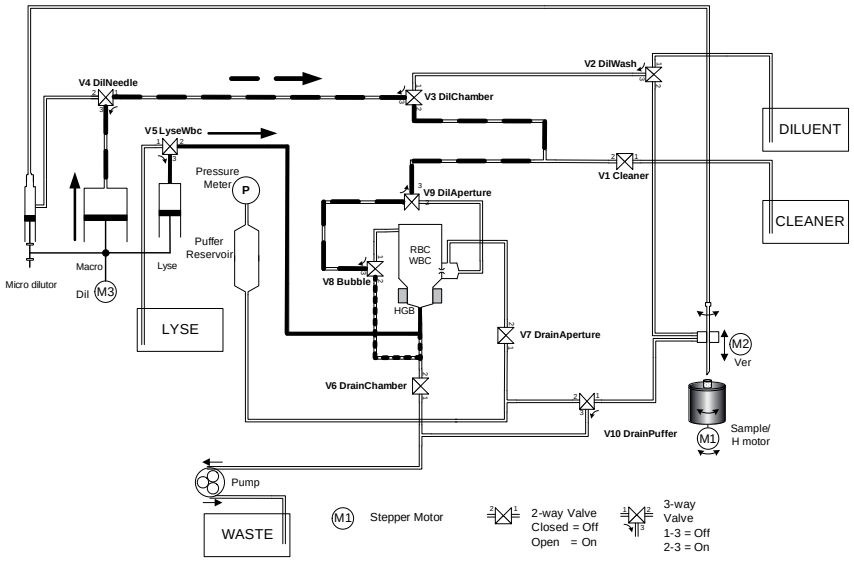


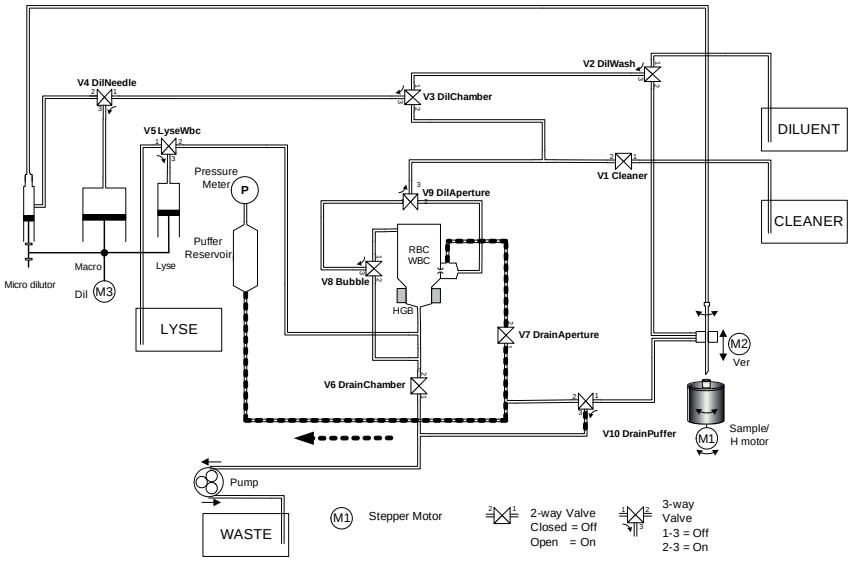
FIGURE 38

For better mixing the macro syringe pushes some air bubbles (aspirated through the washing inlet of the chamber and V8) after the lysing process through V4 (Off), V3 (On), V9 (Off) V8 (On).

5.2.6 COUNTING PROCESS

The regulated vacuum (it is generated by the pump in the puffer reservoir) aspirates the diluted sample (WBC or RBC) from the chamber through V7 (On) valve. There is no volume limiter in the system, the instrument counts the cells for 8.5 seconds in both counting phases (WBC and RBC).

FIGURE 39



For noise prevention there is no mechanical or electronic activity during the counting process and the door should be closed for better shielding.

5.2.7 CHAMBER DRAINING PROCESS

Chamber draining is made under pressure control. Pump drains chamber while puffer reservoir and thus the pressure sensor is connected to the draining tube. The instrument can detect the empty state of the chamber from drop of vacuum

.

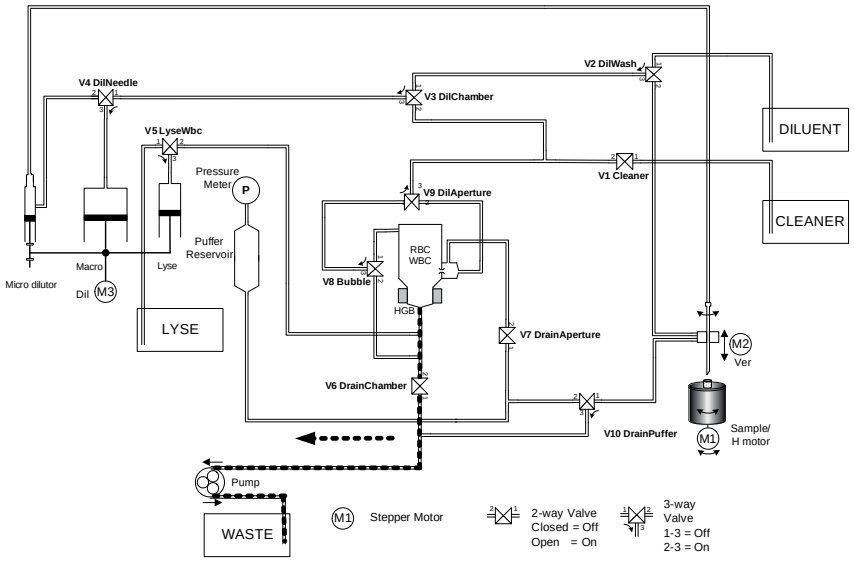


FIGURE 40

5.2.8 SHUTDOWN PROCESS

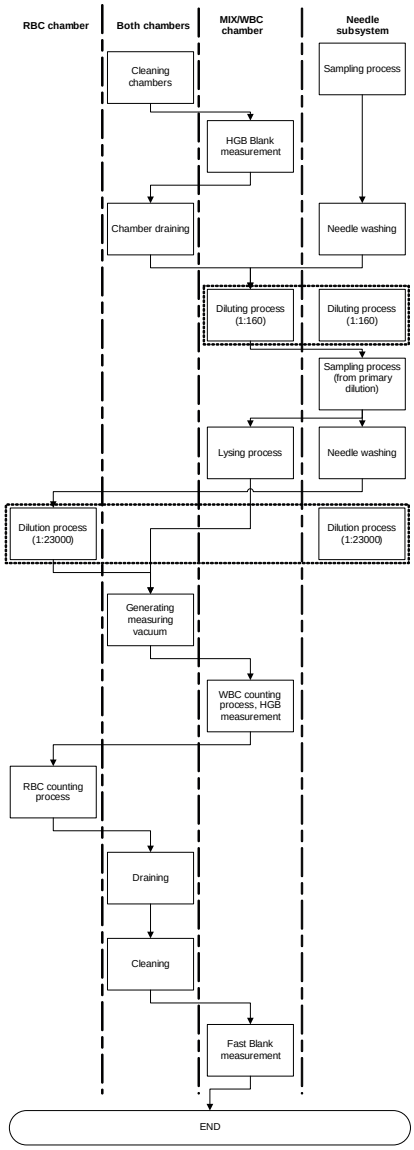
The fluidic shutdown performs the following steps:

- Priming chamber with reagent to avoid drying out of aperture
- Sampling needle is positioned above counting chamber, needle up
- Lyse syringe are positioned up
- Diluent syringes are positioned up
- Sample rotor moved out

5.3 Operation of the fluidic system in HC60TS

The HC60TS fluidic system operates in two parallel pneumatic processes. The first subsystem consists of the following components: Microdilutor, Diluent I. dilutor, V1 valve, washing head, Pump 2. This subsystem is marked with a dotted line outline in the charts. The second subsystem consists of the remaining fluidic components. Thanks to this two parallel subsystems the measuring is could be started during the chamber washing processes. The separate RBC and MIX/WBC chambers make two different diluents mixes possible simultaneously.

FIGURE 41
Flow diagram of measurement



5.3.1 SAMPLING PROCESS

The aspirating needle aspirates 25 µL (50 µL in prediluted mode) of blood sample. The Micro dilutor syringe makes the aspirating while the M3 Micro-dilutor motor moves down. The syringes are mechanically connected with a loose mechanism, so there is a phase along the track, where the micro dilutor doesn't move.

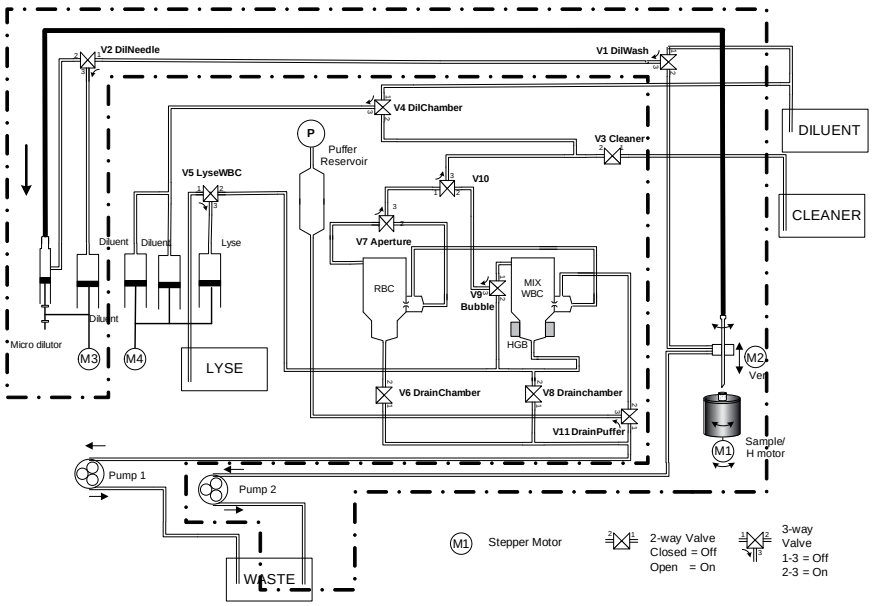


FIGURE 42

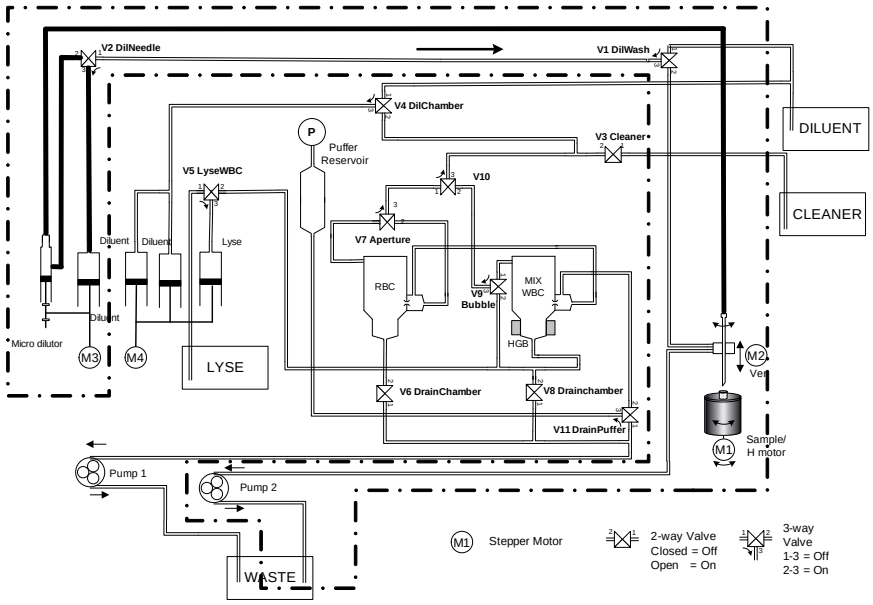
The second sample – 35 µL of primary dilution – is made in the RBC chamber. The instrument makes the second (RBC) dilution into the chamber after straight after the WBC dilution.

5.3.2 DILUTING PROCESS

The parts of the fluidics are rinsed with diluent reagent. The measuring chamber is filled up with 1 ml of diluent. This method prevents the chamber from dirt and makes the diluting process faster.

The sampling process has aspirated 25 µL of sample, which is in the sampling needle. In the first diluting step the sample is dispensed into the measuring chamber with 3 ml of diluent, which comes from the Diluent I. syringe through V2 (On) and Micro-dilutor, while the M3 Dilutor motor moves upwards. This process makes the 1:160 first dilution rate in the chamber.

FIGURE 43

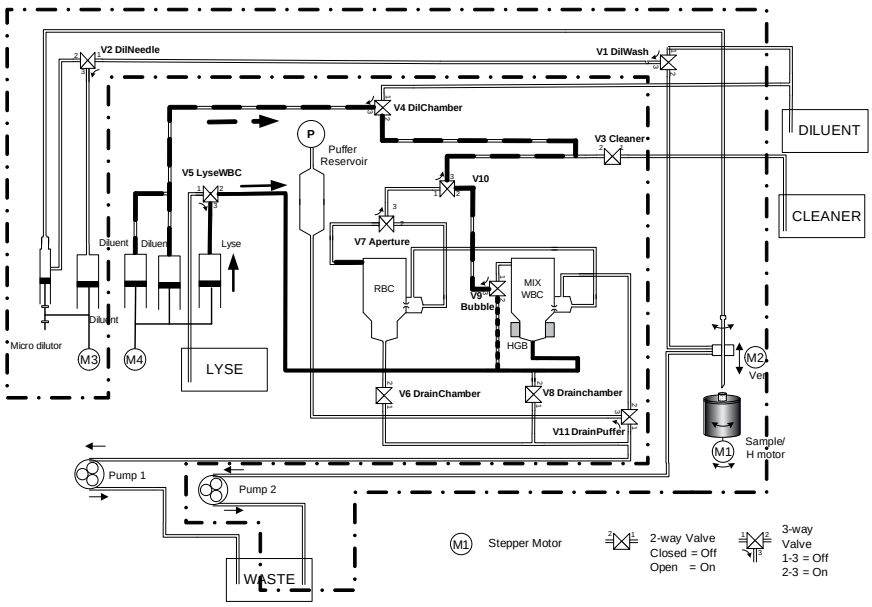


The second sample – 25 µL of primary dilution – is made right after the first dilution. The second dilution is made in the RBC chamber.

5.3.3 LYSING PROCESS

In this step the set lysing reagent is added into the measuring chamber through V10 (On), while the Lyse syringe moves upwards. This process makes the WBC/ HGB dilution with lyse reagent.

FIGURE 44

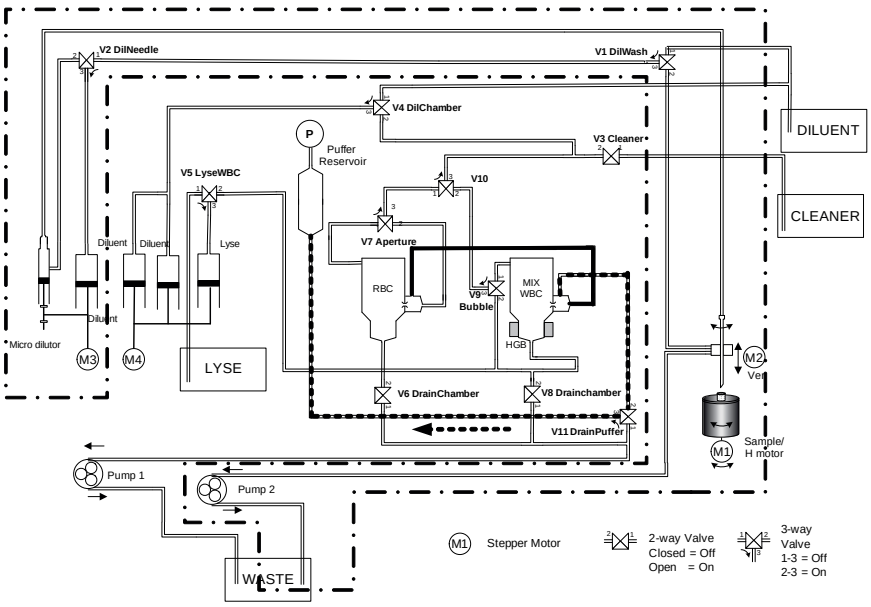


For better mixing the macro syringe pushes some air bubbles (aspirated through the washing inlet of the chamber and V9) after the lysing process through V4 (Off), V10 (On), V9 (Off).

5.3.4 COUNTING PROCESS

The regulated vacuum (it is generated by the pump in the puffer reservoir) aspirates the diluted sample (WBC or RBC) from the chamber through V11 (On) valve. There is no volume limiter in the system, the instrument counts the cells for 16 seconds in counting phases (WBC and RBC).

FIGURE 45



For noise prevention there is no mechanical or electronic activity during the counting process and the door should be closed for better shielding.

5.3.5 CHAMBER DRAINING PROCESS

Chamber draining is made under pressure control. Pump drains chamber while puffer reservoir and thus the pressure sensor is connected to the draining tube. The instrument can detect the empty state of the chamber from drop of vacuum.

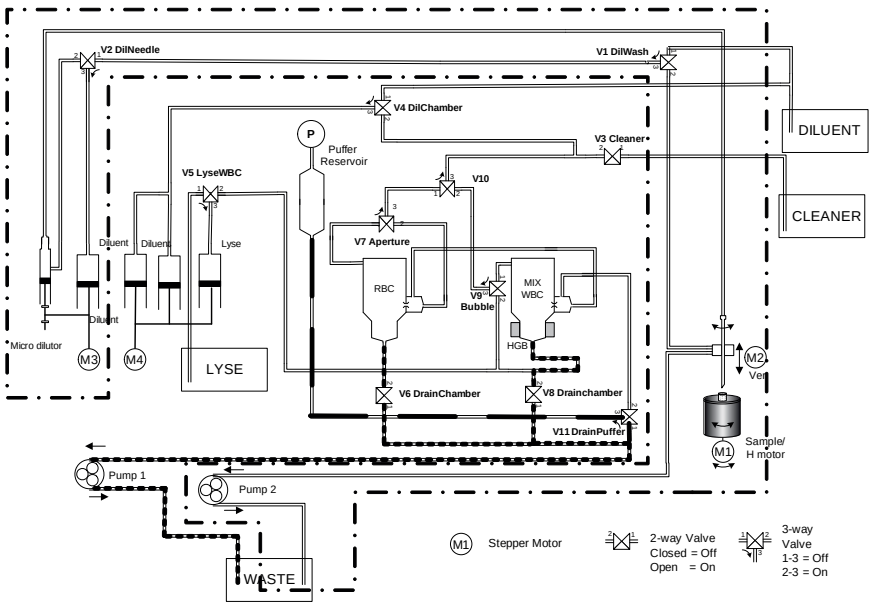
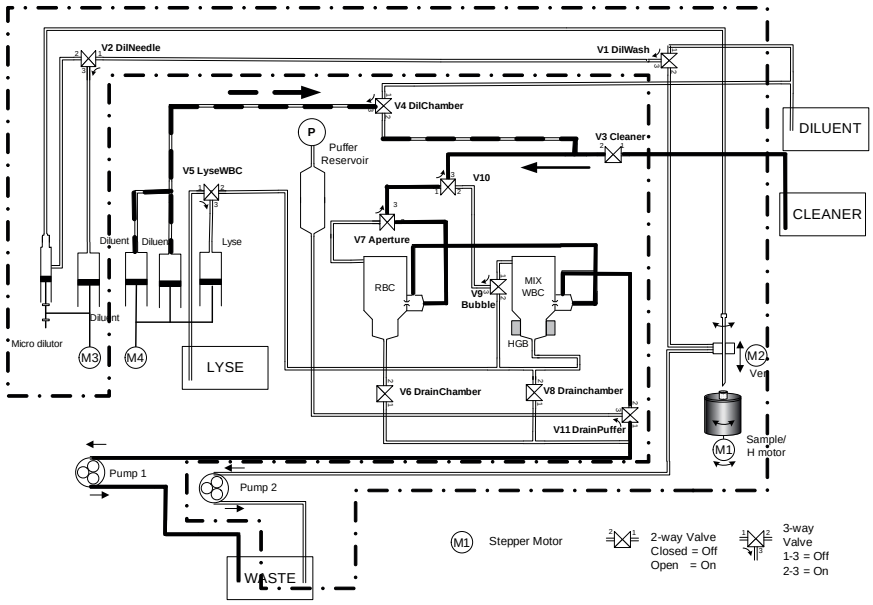


FIGURE 46

5.3.6 CLEANING PROCESS

The pump aspirates the cleaner through the V3 (On), V10 (On), V7 (On) valves to puffer the cleaner reagent in the tubes between V10 and V3.

FIGURE 47



After that the Diluent 2 syringes pushes the cleaner reagent remaining in the tube between V10 and V3 into the chamber.

5.3.7 SHUTDOWN PROCESS

The fluidic shutdown performs a fluidic system cleaning with cleaner.

6 ADJUSTMENTS

The adjustments below are made in the factory. Readjustment of following parts is necessary if some components are replaced.

6.1 Common adjustments

6.1.1 VERTICAL MOVEMENT, SETTING TIMING BELT TENSION

The timing belt tension could be set with positioning the vertical motor using the oval holes in the mounting plate.

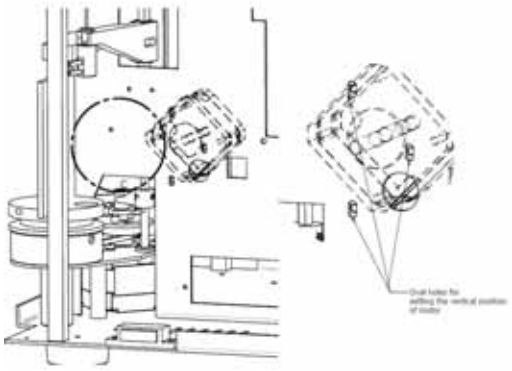


FIGURE 48

6.1.2 VERTICAL OPTO SENSOR AND NEEDLE SETTINGS

The vertical opto sensor should be set as follows:

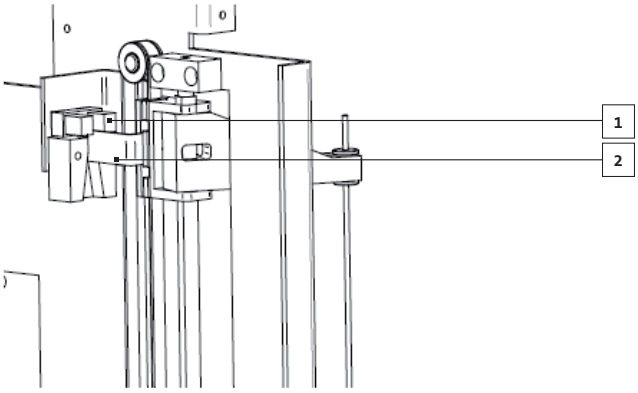


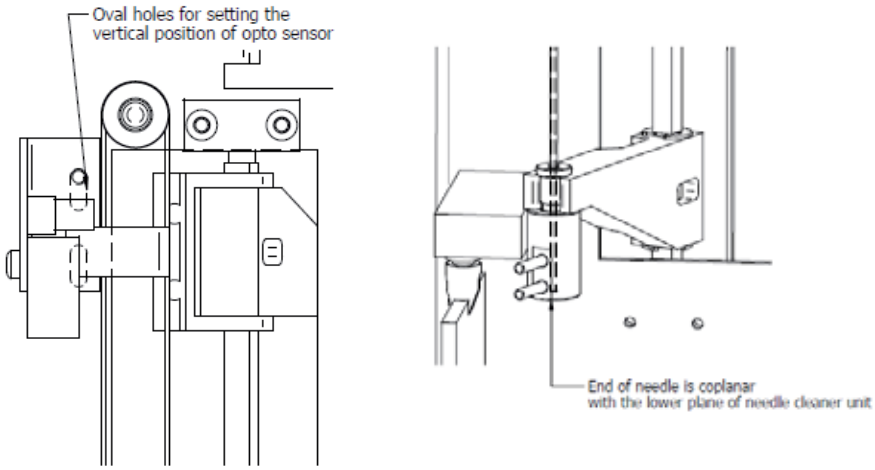
FIGURE 49

1 opto sensor
2 flag

The flag (1) mounted on the vertical needle moving mechanism must run freely between the two parts (2) of the opto-sensor.

The vertical position can be set by loosening the two mounting screws of the opto sensor and moving it up or down. In the correct setting the end of the needle is coplanar of the lower plane of needle cleaner unit. The opto sensor state could be checked in the software (see chapter 8.2.4)

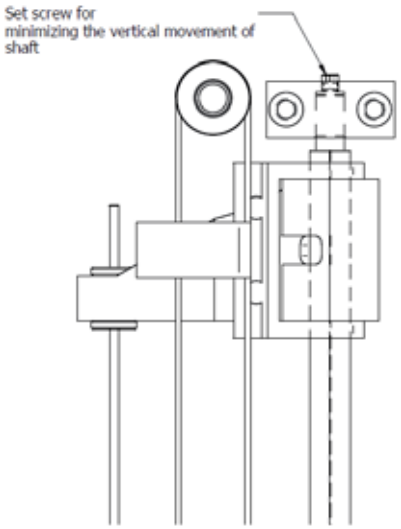
FIGURE 50



6.1.3 SETTING THE NEEDLE SHAFT

The needle shaft must be fastened. If it was loose it could be adjusted with the set screw on top end of the shaft.

FIGURE 51



6.1.4 SETTING THE POSITION OF THE CHAMBERS

After setting the needle position according to chapter 5.2.2 and 5.3.1. the horizontal position of chamber bracket should be checked. The needle must not go down exactly in the center of the chamber. Chamber bracket can be moved left or right if necessary. (see picture).

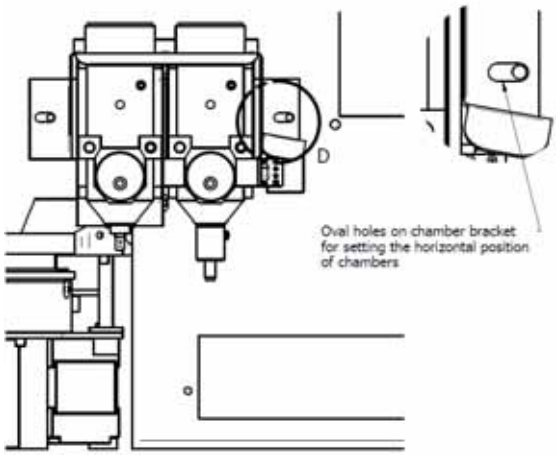


FIGURE 52

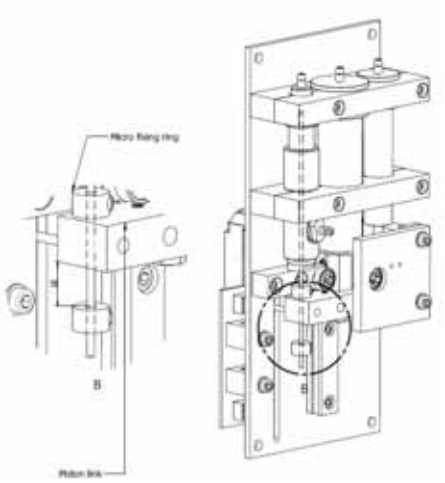
6.2 HC30TS specific adjustments

6.2.1 SETTING THE DILUTOR MECHANICS

The micro-dilutor's movement must be set by the following procedure:

1. Push the dilutor pistons up as possible.
2. Fasten the set screw of the upper fixing ring.
3. Fasten the lower fixing ring's set screw in the position shown in picture on the left.

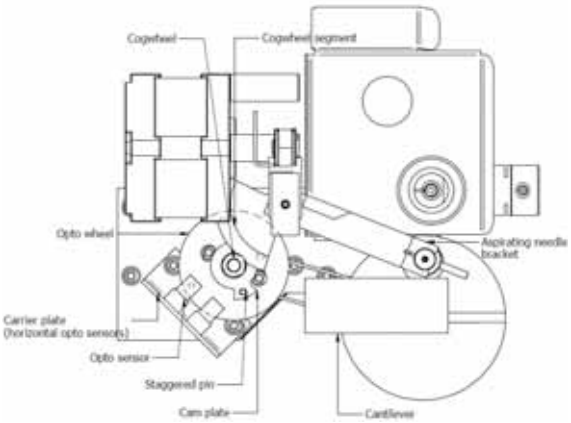
FIGURE 53



6.2.2 SETTING THE HORIZONTAL MOVEMENT

The setting of the horizontal movement is correct, when the opto wheel is in the position shown in the picture, then the aspirating needle bracket is as close to the cantilever as possible.

FIGURE 54



6.3 HC60TS specific adjustments

6.3.1 SETTING THE DILUTOR MECHANICS

The micro-dilutor's movement must be set by the following procedure:

1. Push the dilutor pistons up as possible.
2. Fasten the set screw of the upper fixing ring.
3. Fasten the lower fixing ring's set screw in the position shown in picture on the left.

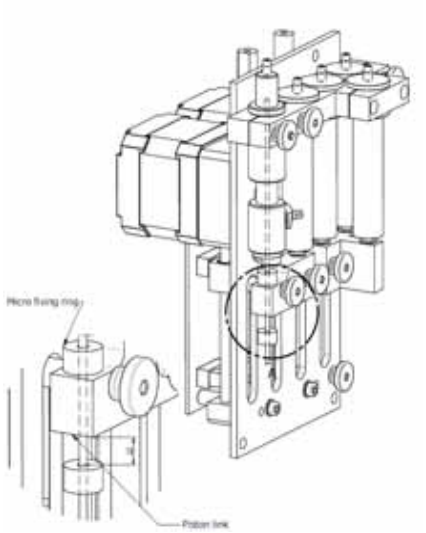


FIGURE 55

6.3.2 SETTING THE HORIZONTAL MOVEMENT

The setting of the horizontal movement is correct, when the opto wheel is in the position shown in left picture, then the aspirating needle bracket is as close to the cantilever as possible.

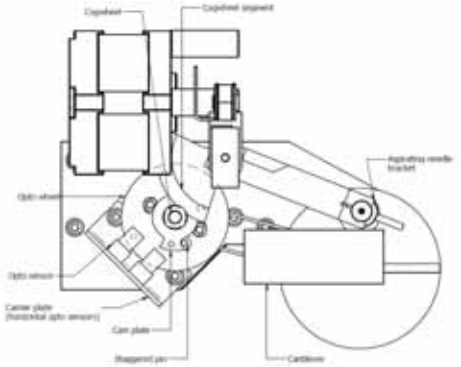
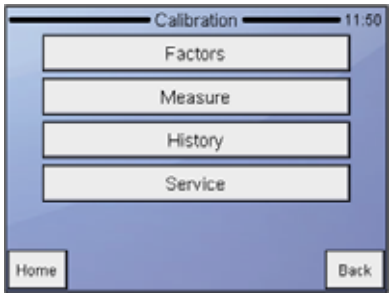


FIGURE 56

6.4 Service Calibration

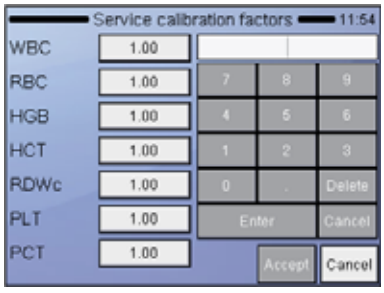
The analyzer provides a menu for Service calibration purposes.



You can access the service calibration menu logged in as Service User: **Maintenance-->Calibration-->Service**.

Factors: In result calculations the service calibration factors are used as the user calibration factors, so they are multiplied for each parameter: RBCDisp. = FactRBC User * FactRBC Serv. * RBCMeasured

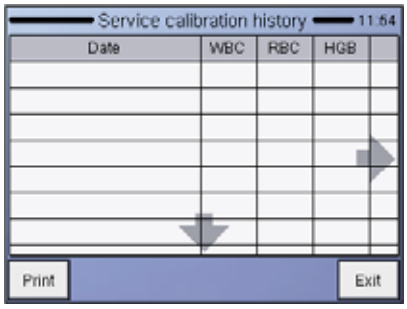
If the user factor is near the bound (0.80 - 1.20), by setting the corresponding service factor, the user factor can be adjusted to 1.00 using **Apply user factors** button. Example: Fact RBC User = 1.19 and Fact RBC Serv = 0.96, and Fact RBC User = 1.00 and Fact RBC Serv = 1.14 gives the same result for RBC.



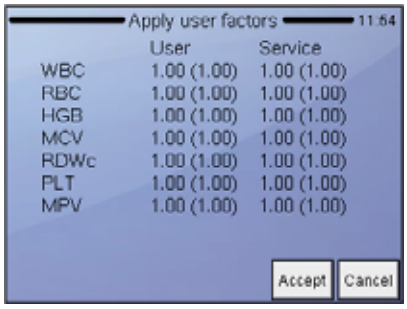
Press white data field to modify calibration factor. A numeric input screen will show up so that you can enter values.

All values must be in the 0.8...1.2 range.

Press Accept to proceed with new settings, or Cancel to keep values unchanged.



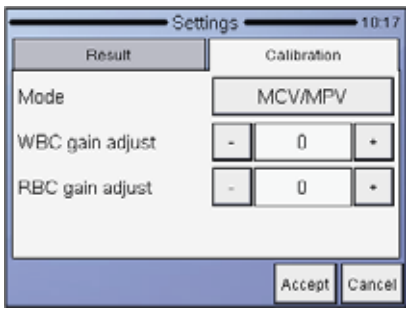
History: You can check the previous calibration factors with the date of change in a table form.



Apply user calibration factors function is used to combine user and service calibration factors. The software will multiply the existing factors, and move them to the Service level to set user factors to 1.00.

6.5 Setting RBC amplifier gain

If the correct MCV value cannot be obtained by calibration the amplifier gain of RBC measurement could be increased or decreased by approx. ±10%. Please be advised that changing this value requires to recalibrate the device to get proper results! The settings are under **Settings-->Measurement-->Setting-->Calibration**.



6.6 Setting WBC amplifier gain

If the WBC diagram is shifted too far on left or right in WBC histogram the amplifier gain of WBC measurement could be increased or decreased by approx. ±10%. Please be advised that changing this value requires to recalibrate the device to get proper results!

The settings are under **Settings-->Measurement-->Settings-->Calibration**.

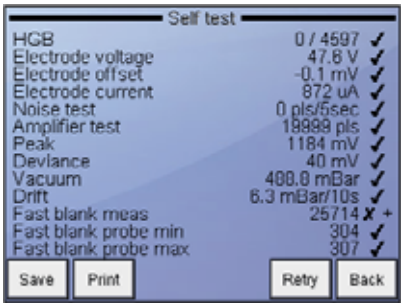
7 CHECKIG THE PROPER OPERATION

7.1 Self Test

There is a built-in Self test and Service menu in each model. Self test can be used to check the operation of the instrument.
The test results can be printed or saved to USB flash disk. With the Retry button the self test is repeated.

7.1.1 SELF TEST SCREENS

Every measured value has a check mark if it is in the acceptable range, or a X and a minus or plus sign if it is below or above the normal range.



HGB measured impulses per second
Measuring **Electrode voltage, current** and **offset**.
Amplifier Noise test during a 5-second period.
Amplifier transfer by generating 20000 test pulses, incl. gain related peak value, noise related **dev**iation.
Vacuum reports pump operation (vacuum made by the pump in a 10-second period of time).
Drift represents pressure loss of vacuum measured in a 10-second period of time.
Fast blank meas, the device performs a fast blank measurement. This number is the PLT count. **Probe min**, **probe max** probe voltage are relative numbers during fast blank measurement.

7.1.2 NORMAL RANGE OF SELF TEST PARAMETERS

TABLE 1

Parameter	Unit	Lower bound	Upper bound
HGB light	count	3000	60000
Electrode voltage	V	45	55
Current	µA	830	930
Offset	mV	-5.0	5.0
Amplifier test	count	19990	20050
Peak of test pulses	mV	1300	1700
deviation (noise)	mV	0	100
Noise test	pls/5sec	0	50
Vacuum	mBar	300	600
Drift	mBar/10sec	0	10
Fast blank meas	count	0	100
Fast blank probe min	-	280	360
Fast blank probe max	-	280	360

7.1.3 TROUBLESHOOTING GUIDE FOR SELF TEST

TABLE 2

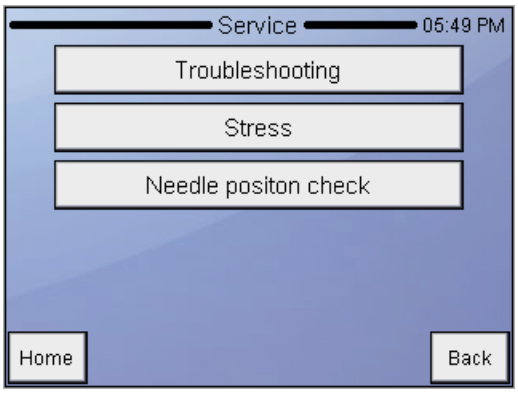
Parameter	Mark	Possible reason	Remedy
HGB dark	HIGH	Instrument door open	Close instrument door
HGB light	LOW	HGB head not connected or HGB LED out of order	Check HGB head connections. Check HGB LED during measurement
	HIGH	Instrument door open or HGB LED too bright	Close door or replace HGB LED resistor on amplifier board
Electrode voltage	LOW or HIGH	Fault on MAIN or Amplifier board	Check measuring voltage (50V) on High voltage and Amplifier boards
Current	LOW or HIGH	Fault on Amplifier board	Check current generator, and test generator FET on Amplifier board
Offset	LOW or HIGH	Fault on Amplifier board	Check the offset poten-tiometer on Amplifier board
Amplifier test	LOW	Amplifier Boards is not connected to main board	Check cables and connectors coming from the Amplifier
	HIGH	Instrument not grounded	Check mains ground lead

Peak of pulses	LOW or HIGH	Fault on Amplifier board	Check current generator, and test generator FET on Amplifier board
Dev. (noise)	HIGH	Instrument not grounded	Check mains ground lead
Noise	HIGH	Instrument not grounded	Check mains ground lead
Vacuum	LOW	Peristaltic pump failure	Check peristaltic pump
Drift	HIGH	Leakage in pneumatics	Check tubing in pneumatics
Fast Blank meas	HIGH	Contaminated system	Run cleaning cycle
Fast Blank probe min	HIGH or LOW	Fault on MAIN or Amplifier board	Check measuring voltage (50V) on MAIN and Amplifier boards
Fast Blank probe max	HIGH or LOW	Fault on MAIN or Amplifier board	Check measuring voltage (50V) on MAIN and Amplifier boards

7.2 Service Menu

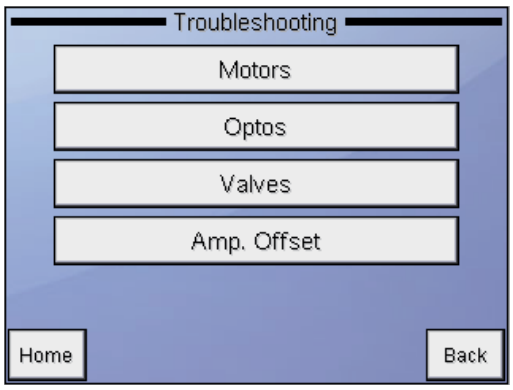
7.2.1 ENTERING TO SERVICE MENU

There is a Service menu for servicing and operation checking purposes.
The entry point is in **Maintenance --> Diagnostics --> Service**
The service menu is accessible for only SERVICE user. To login as service user please see chapter 6.2.5.

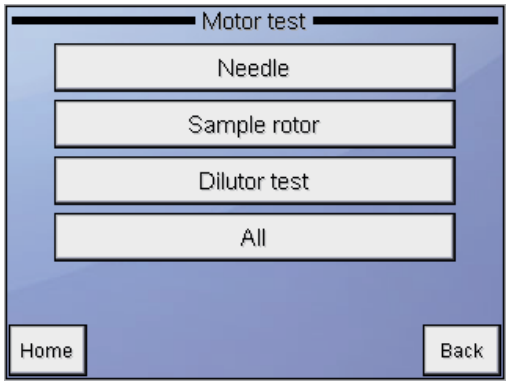


7.2.2 TROUBLESHOOTING

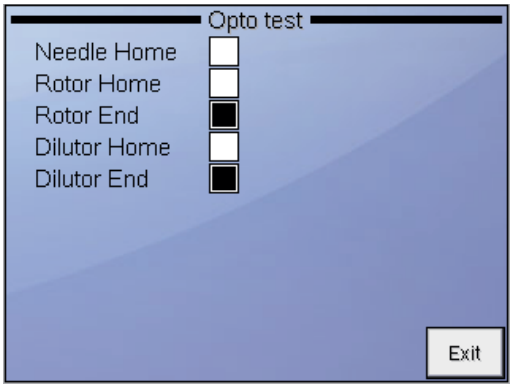
With Troubleshooting options provide tools to test mechanical components.



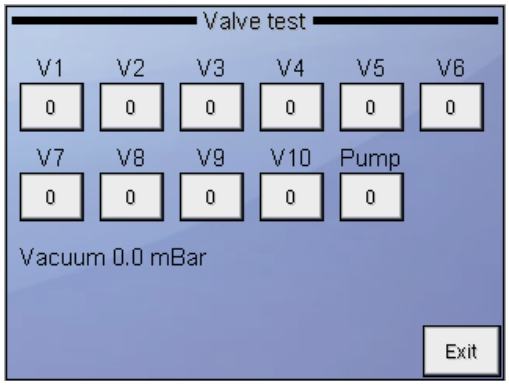
From the Motor Test submenu the service person could run each or all motor tests.



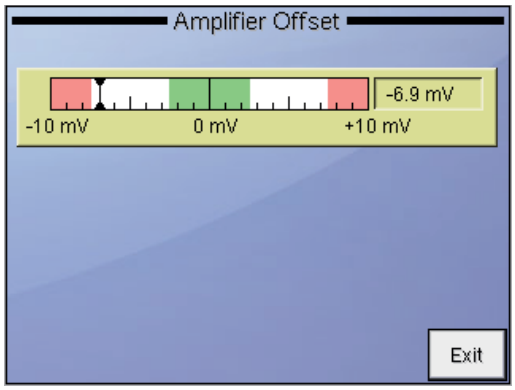
Optosensor's states can be checked in this screen.



Pressing the 0 or 1 buttons the valves could be toggled. 1 stands for electronically forced state.
Pressing the Pump 0 or 1 button the peristaltic pump could be switched on/off.
The current vacuum in the puffer reservoir is displayed under the buttons.



You can check the offset on the amplifier board. The current offset and the acceptance range are displayed.



7.2.3 STRESS

In Stress mode, the instrument performs measuring cycles without sample (blank measurements) continuously. This can be used for burn-in tests, or to check pneumatic system after changing any main fluidic parts.
You can have information about stability, cleanliness, HGB operation, and counting time stability. Results of the PLT and HGB blank results are displayed in table format.

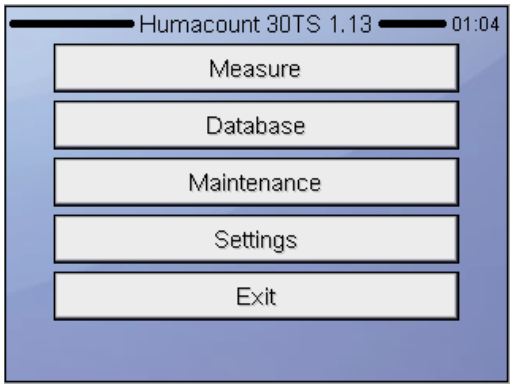
You can detect any kind of noise, or bubbles in the system if the PLT is not stable low, or HGB has big variation. To exit from this mode **press the Abort button** (at the end of a normal cycle) until the Stress operation is finished.

7.2.4 NEEDLE POSITION CHECK

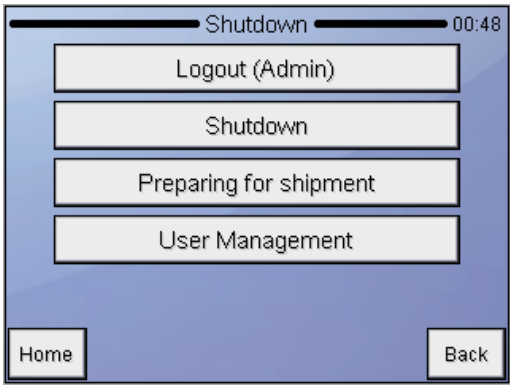
The service personal can check the correct needle setting touching Needle position check button. If the needle opto is set correctly, then after the button touch the needle lower end is co-planar with the bottom plane of the washing head. If it doesn't then adjust the needle opto up or down and check the position again.

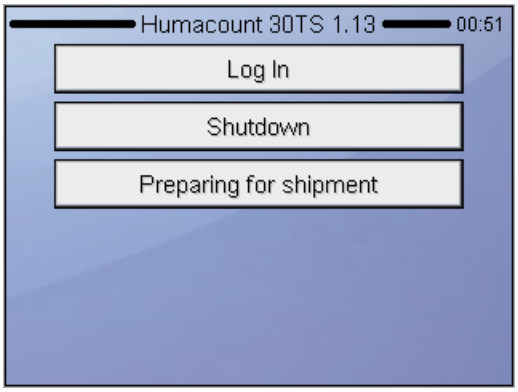
7.2.5 LOG IN AS SERVICE USER

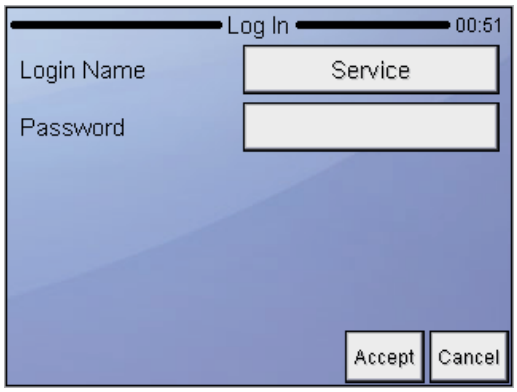
Certain service functions are accessible only for the SERVICE user.
In Main menu touch **Exit** button.



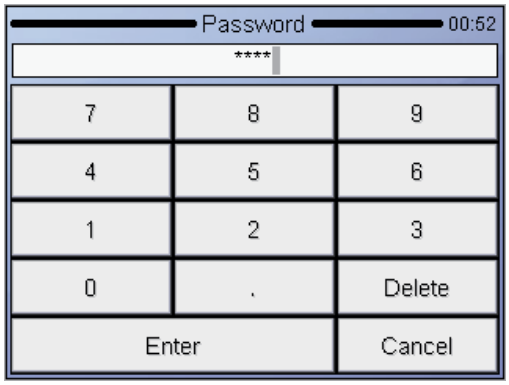
If you are logged in as different user touch **Logout(USERNAME)** and then the **Log In button**, else touch **Log In** button.







At Log In screen Press the START button on front panel, so the Login Name will change to Service.
Touch Password empty field.



Type in the Service User password which is **6484**, then touch Enter button.
Touch **Accept** button on Log In screen.

8 SERVICE OPERATION

8.1 Possible Causes of Noise

Generally high count of any particle - even if you think it should be low, or near zero - can be caused by noise, i.e. something interfere with the measurement.
The most important thing in these cases is to identify the source of the noise, otherwise you cannot protect the system against it.
Noise can come from several sources, and the different sources add up. However only one of them may be enough to cause problems.

8.1.1 CONTAMINATED REAGENT

The most probable cause are particles in the reagent, and therefore the PLT blank is continuously high (e.g. always 30-40). You can easily sort out this case by replacing diluent with a new container. PLT blank must go down during several blank measurements (below 10).

How can a good reagent become bad with time?

- If the reagent tube was contaminated, and some bacteria begin to grow inside, once you put an infected reagent tube into a new tank, by time it can become infected as well, i.e. the background (PLT blank) becomes high. Wash the reagent tube - which is in connection with the reagent - with 1% of bleach solution, then rinse with clean distilled water or diluent. It can avoid the bacteria to grow inside.
- If container is open – and cap is not installed or closed - external dust can fall into the reagent.

8.1.2 BAD EARTH GROUNDING

In this case external - ground referenced - noise can get into the system by ground coupling. If system ground is not good enough, ground terminal can become a noise source as well, i.e. external signals will be coupled into the system instead of protecting it.
If no earth ground is available, you can use a screw at the rear panel to connect a ground potential to the case, so that noise immunity can be increased.
Measure voltage on ground terminal to make sure earth grounding is correct. AC voltage lower than 1V is accepted in this case.
At some places - as a bad practice - electricians like to connect earth ground terminal to neutral wire. Depending on the resistance of the neutral back wire (where it is really earthed), several volts can appear, and this way any

inductive noise will be coupled into the instrument. It is better to create a real earth grounding and connect it to the rear screw.

8.1.3 EXTERNAL ELECTRICAL NOISE

If another instrument is near the analyzer can radiate electromagnetic signals in the 1 kHz - 100 kHz frequency region it can be picked up by the system (especially if they are very close to each other, or the grounding is not quite perfect).

You can easily identify this noise source: by relocating the instrument noise (high PLT blank) disappears. In this case you have to identify the possible noise source (switch mode power supplies, computer monitors, since they are not shielded, centrifuges due to high switching noise of rotor contacts, etc.), the power of the electromagnetic source, because if high power is present, maybe relocation does not solve your problems, sometimes the electric power supply makes the coupling, so UPS solves the problem.

Another source of coupling in external noise can be the reagent tanks and tubes. Especially radio transmitters can cause problems of radiating so that even the reagents (diluent) guides in the noise. A metal pack for the diluent tank, then a good earth grounding of this metal box allows this coupling to disappear forever.

8.1.4 INTERNAL NOISE SOURCES

The most annoying but real cause is some sort of internal noise. The reason for this phenomenon is that inside electrode - hot point - of the measuring circuit must be well insulated from surrounding electronics, otherwise inside noise sources can take their effect.

8.1.4.1 Bad chamber insulation:

- **Bad shielding of the chamber** (floating shield couples signals to the chamber, and does not prevent against them). Check grounding of shield, remove it and clean the surface between the shield and the metal base.
- **Bad reference electrode connection** (floating ground reference). Repair is required.
- **Bad sealing of aperture.** Replacement of measuring tube is required.
- Broken measuring chamber starts to conduct through the gaps (ground path). Replacement of chamber is required.
- **Contaminated draining tube** starts to conduct due to protein or lipid build-up. It is very easy to identify this case. After replacing the drain tube of the

measuring chamber (mainly WBC), WBC histogram peak, or PLT becomes low soon. Normally a good cleaner is required to dissolve lipid or protein build-up. Sometimes the cleaner is not strong enough to keep this tube clean enough. Periodic washing using 1% hand warm bleach solution helps.

8.1.4.2 Bad insulation of electronic signal paths:

In these cases check for any capacitive coupling of electronic signals to the chamber:

- **Interference with HGB head** (high-frequency signal is coupled to the chamber). HGB head metal parts must be grounded. The ground comes externally, it must be in place, otherwise HGB head does not shield, but couples in noise.
- **Interference with internal high voltage inverter** (high-frequency signal is coupled to the chamber). Repair is required: avoid near contact of HVB cable to chamber or shielded amplifier cable.
- **Interference with internal start button** (polling signal to start button may cause noise). Guide start button wires as far from chamber as possible. You may try mix them up on the start micro-switch if applicable.
- **Interference with display cable** (high-frequency LCD signal is coupled to the chamber by the ribbon cable). Keep the ribbon cable far from the chamber.
- **Interference with CPU fan or other digital logic traces** (CPU fan or other digital signal radiates to chamber or to the shielded amplifier cable). Try keeping the ribbon cables far from the chamber and shielded cable.

8.1.4.3 Bad components or connections:

- **Bad soldering, salt residuals or component failure on amplifier** (especially if some reagent could get in the amplifier section). Cleaning of PCB/electrode socket or replacement of amplifier is required. Check for the correct soldering of reference cable and its connector.
- **Circuit board bad soldering or component failure.** Check the shielded cable connections as well. Sometimes inside out connection (hot electrode goes outside as a shield) is the problem: both ends of amplifier signal cable must be reversed.
- **Analog signal ribbon cable** (it picks up noise). Check the ribbon cable between the circuit board and the amplifier. Maybe it is pinched under some screws or components. This may cause trouble and even noise.

8.1.4.4 Pneumatic failures, liquid paths that conduct noise into the chamber:

- **Liquid remains under the chamber in drain tube** (during measurement the conducting liquid remains inside the drain tube making noise to appear there).

  - Check chamber draining path for clogging or salt crystals.
  - Check the pump operation. Since draining of the chamber goes under pressure control, maybe a bad pressure sensor or connection can cause trouble.
  - Clean the draining path. Do not use alcohol, but bleach. Replace chamber if necessary.

- **Liquid remains in the washing inlet at top of the chamber** (during measurement the conducting liquid remains inside the chamber wash tube making noise to appear). The software is not compatible with the mechanics, or related valve is bad/partly clogged, or the tubing is clogged/loose.
- **Lyse path guides in noise** (during counting, if the a liquid in the draining tube is touching lyse reagent in T-fitting, noise can appear). Check the lyse path, and the lyse valve as well.

9 MAINTENANCE

9.1 Weekly User Maintenance

Perform weekly maintenance before turning on the power switch. The right side has a side door giving access to the fluidic system and the mechanical parts easily.

9.1.1 CLEANING NEEDLE WASHING HEAD

Needle washing head cleans the outer surface of the aspirating needle with diluent.

Any salt build-up on the lower surface may cause malfunction during operation. Use a soft cloth or wiper dampened with water to clean this area. You can see the washing head indicated in the following figure:

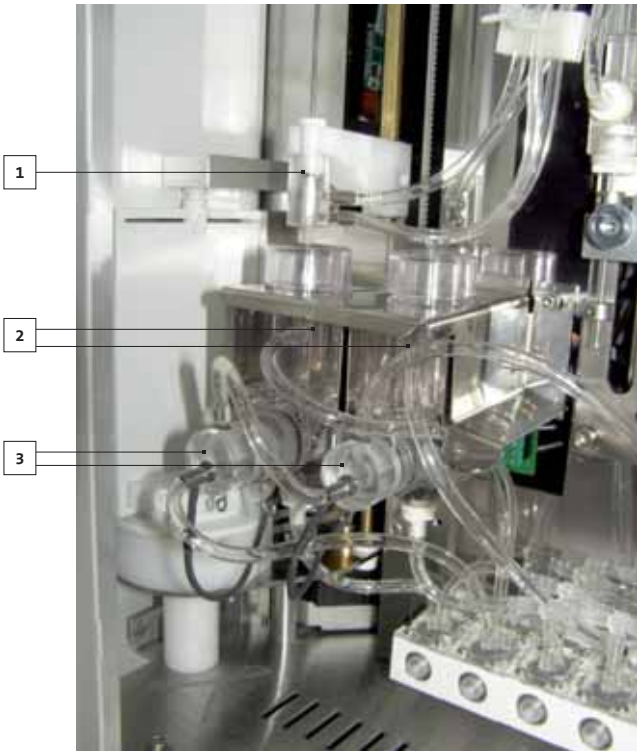


FIGURE 57
HumaCount 60 TS chambers

1 **Washing head**
2 **Measuring chambers**
3 **Measuring apertures**

FIGURE 58
HumaCount 30 TS chamber

1 Wash head
2 Measuring chamber

1. Exit Measure menu. Open the side door after the needle has stopped moving.
2. Gently rub the lower surface of the washing head with a damp cloth or wiper to remove the salt build-up.
3. Close the side door.

9.2 Periodic Maintenance by Service

The instruments should be checked and maintenance must be carried out in every 6-12 months, or after 10 000 measurement cycles.

9.2.1 CHECK SELF TEST AND DEVICE STATISTICS

Run the built-in Self test and check the overall test result. Check the device statistics to find common problems.

9.2.2 CLEANING AND GREASING DILUTOR BLOCK

The dilutor block driving wheels and gear bar should be cleaned from dirt and must be greased between the gear bar and the support, and between cogged wheels.

9.2.3 CHECKING AND LUBRICATING DILUTOR PISTON TIPS

The cogged end of PTFE dilutor pistons should be cleaned and lubricated by neutral silicon grease. Apply just a thin layer, and move it along the perimeter of the piston, so that some of the material goes into the gaps between the sealing rings.

Repeat this step for lyse and dilutor pistons as well. Check the condition of the micro piston sealing, and replace if necessary.

9.2.4 CHECKING AND REPLACING WASHING HEAD

Check the state of the washing head, and replace if necessary. After replacing washing head, do not forget to perform correct adjustment of sampling needle height (see Section 4.1.2).

9.2.5 BLEACHING OF FLUIDIC SYSTEM

It is recommended to run a bleaching procedure to remove stains from the fluidic system.

1. Connect 2-5%, hand warm, clean bleach solution to all reagent inputs, and perform priming on all reagent inputs.
2. Leave it in the tubing for not more than 2-3 minutes.
3. Remove the bleach, prime on air.
4. Connect distilled water (100 ml), and perform priming all reagents, again. Connect reagents, and run priming again.

10 APPENDICES

10.1 Warning flags

Analyzer SW displays **warning flags** for each individual measurement to notify user about status of results. The following table summarizes **warning flags** and gives explanation of their possible cause and a few hints to overcome the problem.

Uppercase letters refer to WBC or HGB problems.

TABLE 3
Summary of warning flags related to WBC/HGB

Flag	Meaning	Recommended user action
E	No WBC 3-part differential	Possible lyse problem. May occur in pathological lymphocytosis.
H	HGB blank is high, or no HGB blank	Repeat the blank measurement. If HGB blank is not stable there are probably bubbles in the WBC chamber: Run a cleaning and try blank again. Close the side door if open during measurement.
B	WBC blank is high, or no WBC blank	Repeat the blank measurement, or run prime lyse and try blank again. Possible lyse contamination, or noise problem.
M	linearity range exceeded in WBC stage	The analyzer found that the cell count is higher than the linearity range of the analyzer. Make a pre-dilution, and run the same sample in prediluted mode
R	RBC cells found in sample during WBC stage	RBC cells were detected during the WBC measurement. Either the lyse reagent is not effective enough (volume should be increased) or the RBC's in the sample are somewhat lyse resistive
W	WBC 3-part warning	Probably large PLTs or clumped PLTs are present in the sample. Usually caused by the nature of the sample. cat and goat samples tend to clump. Intensive, but careful mixing of the sample (e.g. Vortex) can help remove the clumps. If the rerun sample gives the same results, consider that WBC and NEU values seem higher because of the clumps. Lyse modification can't solve the problem.

L	RBC-WBC limit warning	Typically insufficiently lysed RBC's interfere with the start of the WBC histogram. Repeating the measurement with an increased lyse volume should provide better separation. If the repeated run reports very similar results then the MON and NEU results are VALID but the WBC and LYM results may be higher because of interfering RBCs.
C	WBC clogging	Aperture clogging. Perform cleaning and repeat the measurement. If it is a general problem, please contact your Service Personnel. Low temperature reagents can cause it as well (mainly diluent), in this case you will have to wait until they reach room temperature.

Warning flags in lowercase refer to RBC or PLT problems.

TABLE 4
Summary of warning flags related to RBC/PLT

Flag	Meaning	Recommended user action
m	linearity range exceeded in PLT/RBC stage	The analyzer found that the cell count is higher than the linearity range of the analyzer. Make a predilution, and run the same sample in prediluted mode
k	RBC peak error	Multiple or incorrect RBC peak(s) detected. Try to run the sample again.
l	PLT / RBC limit not correct	PLT and RBC cells could not be separated, or the histogram remained high in the PLT/RBC valley range.
c	RBC/PLT clogging	The same action as in case of the C warning flag.
p	PLT blank is high, or no PLT blank	Run cleaning and repeat the blank measurement. Diluent or system cleanliness problem. If it is stable high, replace the diluent by opening a new tank.
b	RBC blank is high or no RBC blank	Same action as in case of warning flag p.

10.2 USB B connector communication

The byte stream is a human readable ASCII character stream, with occasional control characters. Most programming environments are able to handle this stream as a simple ASCII string or text. The stream is line-oriented with special characters to separate fields. The protocol has a single format for transmitting a single measurement record. If more records are sent, they are simply chained together one after the other.

10.2.1 CHARACTERS AND BASIC STRUCTURE

The byte stream uses the ASCII characters in the range 1..255 (http://en.wikipedia.org/Ascii), or 0x01..0xFF in hexadecimal.

A record transmission consists of three parts: a small header, a big text body, and a small footer. A single record is never longer than 8192 bytes. A transmission always starts with the control character „Start of Header" (<SOH>, 1, 0x01). The second character is a counter: it will contain a single uppercase English letter in the range „A" to „Z", incrementing with every record. The first record will contain „A", the second will contain „B", etc. If the instrument sends many records without being turned off, the counter will overflow from „Z" to „A". The third character is an identifier: if the instrument is an ABJV5, it will be an uppercase „A", and in case of the HC30/60TS it will be an uppercase „N". The fourth character is the control character „Start of Text" (<STX>, 2, 0x02). The fifth and consecutive characters form the body of the transmission. The body may contain characters from the printable range (32..126, 0x20..0xFF), and the control characters „Horizontal tab" (<HT> or <TAB>, 9, 0x09), „Carriage return" (<CR>, 13, 0x0D), and „Line feed" (<LF>, 10, 0x0A). The body contains several lines separated by a two-byte sequence <CR><LF>. See below for the detailed description of the contents. The body of the transmission is closed by the control character „End of Text" (<ETX>, 3, 0x03).

The footer consists of a two-character checksum in a two-digit hexadecimal form. The checksum is calculated by summing up the values of all characters in the message header and body, including the beginning <SOT> character and the last <ETX> character, adding 255 (hex: 0xFF) to it, and keeping only the last two hexadecimal(!) digits.

The last character of a record is always the single control character „End of Transmission" (<EOT>, 4, 0x04). There is no terminating „NULL" (<NUL>, 0, 0x00) character at the end. The next record can start right after the <EOT> character.

10.2.2 DETAILS OF THE 3.1 PROTOCOL

The body of a transmission is line-oriented, separated by the two-byte „Carriage Return" „Line Feed" (<CR> <LF>, 13 10, 0x0D 0x0A) sequence. A single line might contain one or more fields, separated by the „Horizontal tab" (<HT>, 9, 0x09) character.

The following lines are usually composed of an identifier field and one or more value fields, all separated by the <HT> character. The characters in bold appear in the transmission exactly as written, without any variance between records. Control characters are marked with the < and > characters, for example <HT>. {Comments} are marked with { and }, and are not included in the actual

transmission. For a more detailed discussion on the meanings of the various parameters and histograms, please refer to the instruments' user manuals.

TABLE 5

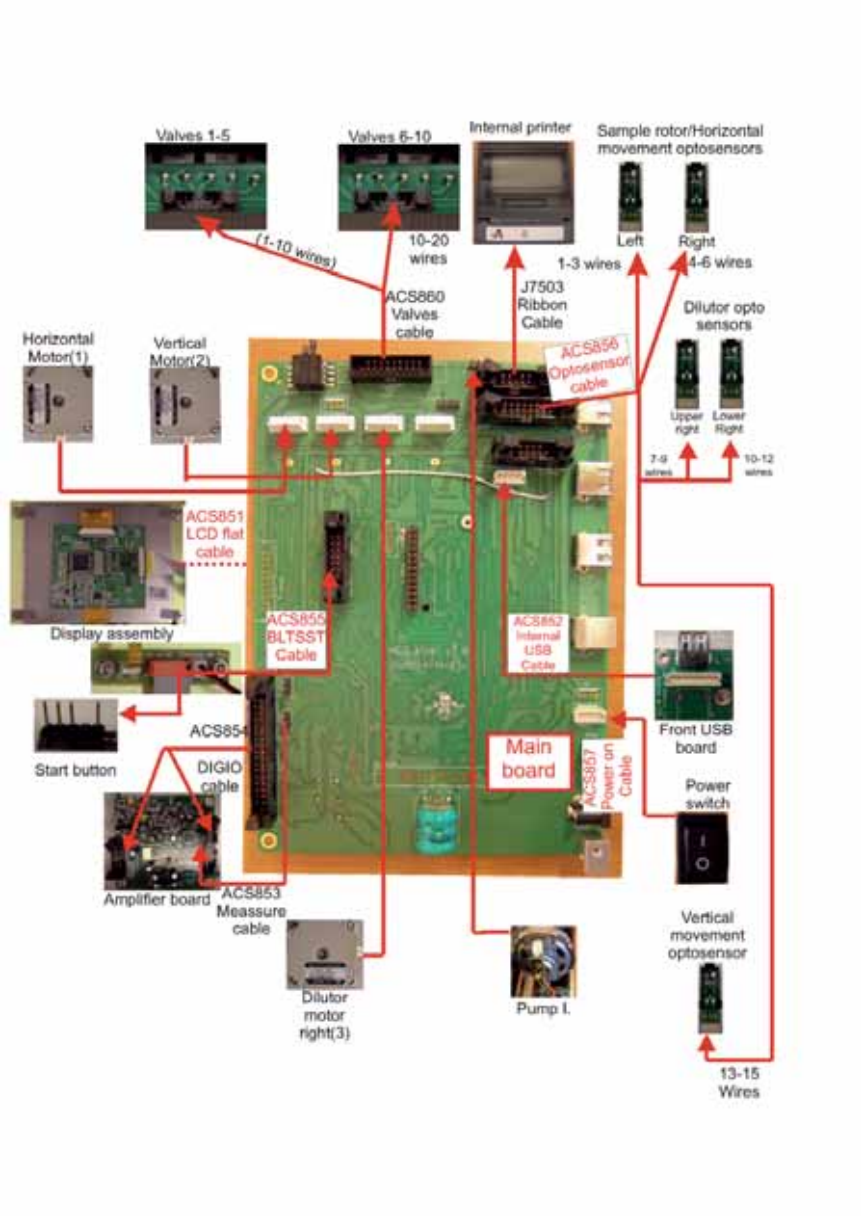
header1 to header 8	header1 to header8 are the lab header lines these lines are defined by the user in the instrument settings any or all of these lines can be empty
Serial No.:<HT>serial	serial is the 6 digit serial number of the instrument
RecNo:<HT>recno	recno is the internal record number, at most 6 digits
Sample ID:<HT>sampleid	sampleid is at most 8 characters long
Patient ID:<HT>patientid	patientid is at most 20 characters long
Patient Name:<HT>patientname	patinetname is at most 32 characters long
Mode:<HT>mode	
Doctor:<HT>doctor	doctor is at maximum 16 characters long
Age:<HT>value<HT>unit	value is a number of at most 3 digits, unit is either „years" or „months"
Birth(ymd):<HT>birthdate	birthdate is an 8 digit number, format: yyyymmdd
Sex:<HT>gender	gender is „Male", „Female", „Neutered", „Spayed" or a single „-" character
Test date(ymd):<HT>date	date is an 8 digit number, format: yyyymmdd
Test time(hm):<HT>time	time is a 6 digit number, format: hhmmss
Param<HT>Flags<HT>Value<HT> Unit<HT>[min-max]	this is a header line, always the same
param<HT>flag<HT>value<HT> unit<HT>[min-max]	There are 24 similar lines: param is the parameter name, at most four characters long, possible values are (in sequence): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, PCT, MPV, PDWs, PDWc, RDWs, RDWc, LYM, MON, NEU, LY%, MO%, NE%, EOS, EO%, BAS, BA% flag is a single character indicator, can be „ " (space), „+", „-", „E" and „*"(asterisk) value is the measured parameter value, exactly 4 characters: number with a possible decimal dot, padded with spaces on the left side, or 4 minus signs „----", or 4 spaces „ " unit is at most 4 characters long, possible values are „10^9/L", „10^3/µL", „10^{12}/L", „10^6/uL", „fL", „%", „g/L", „g/dL", „mmol/L", „pg", „fmol", depending on the parameter. Min and max are the lower and upper bounds of the normal range, exactly 4 characters, including a possible decimal dot, padded with spaces on the left side
Flags:<HT>flags	flags is a series of characters indicating errors, at most 32 characters long, upper or lowercase letters „a" to „z"
WBC graph	always the same, indicates the beginning of the WBC histogram
Scale(fl):<HT>wbcscale	wbcscale is maximum 3 digit number, indicating the fl value of the last channel, value is usually 400

Channels:<HT>wbcchannels	wbcchannels is the number of channels (columns) in the histogram, always 256
WMarker1:<HT>wm1	wm1 is the first WBC discriminator channel (RBC/WBC)
WMarker2:<HT>wm2	wm2 is the second WBC discriminator channel (LYM/MON)
WMarker3:<HT>wm3	wm3 is the third WBC discriminator channel (MON/NEU)
Points:<HT>ch0<HT>...<HT>ch255	chxx is the histogram height at a given channel (range 0..255), there are always wbcchannels values here (usually 256)
RBC graph	always the same, indicates the beginning of the RBC histogram
Scale(fl):<HT>rbcscale	rbcscale is maximum 3 digit number, indicating the fl value of the last channel, value is usually 200
Channels:<HT>rbcchannels	rbcchannels is the number of channels (columns) in the histogram, always 256
RMarker1:<HT>rm1	rm1 is the RBC discriminator channel (PLT/RBC)
Points:<HT>ch0<HT>...<HT>ch255	chxx is the histogram height at a given channel (range 0..255), there are always rbcchannels values here (usually 256)
EOS graph	always the same, indicates the beginning of the EOS histogram
Scale(fl):<HT>eosscale	eosscale is maximum 3 digit number, indicating the fl value of the last channel, value is usually 400
Channels:<HT>eoschannels	eoschannels is the number of channels (columns) in the histogram, always 256
EMarker1:<HT>em1	em1 is the EOS discriminator channel (WBC/EOS)
Points:<HT>ch0<HT>...<HT>ch255	chxx is the histogram height at a given channel (range 0..255), there are always eoschannels values here (usually 256)
PLT graph	always the same, indicates the beginning of the PLT histogram
Scale(fl):<HT>pltscale	pltscale is maximum 3 digit number, indicating the fl value of the last channel, value is usually 50
Channels:<HT>pltchannels	pltchannels is the number of channels (columns) in the histogram, always 256
PMarker1:<HT>pm1	pm1 is the first PLT discriminator channel (PLT start)
PMarker2:<HT>pm2	pm2 is the second PLT discriminator channel (PLT/RBC)
Points:<HT>ch0<HT>...<HT>ch255	chxx is the histogram height at a given channel (range 0..255), there are always pltchannels values here usually 256)

As mentioned above, after the last channel value in the PLT histogram the body of the record is closed with the control character „End of Text" (<ETX>, 3, 0x03).

10.3 Cabling diagram

FIGURE 59
HC30TS cabling diagram



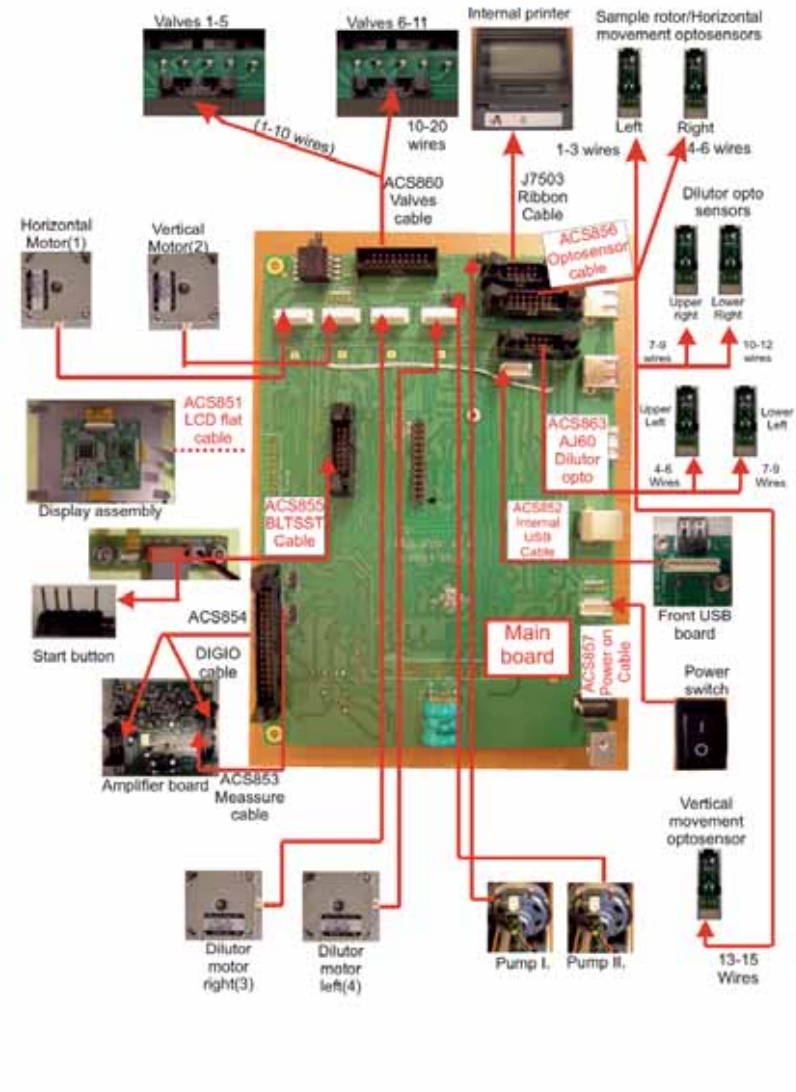


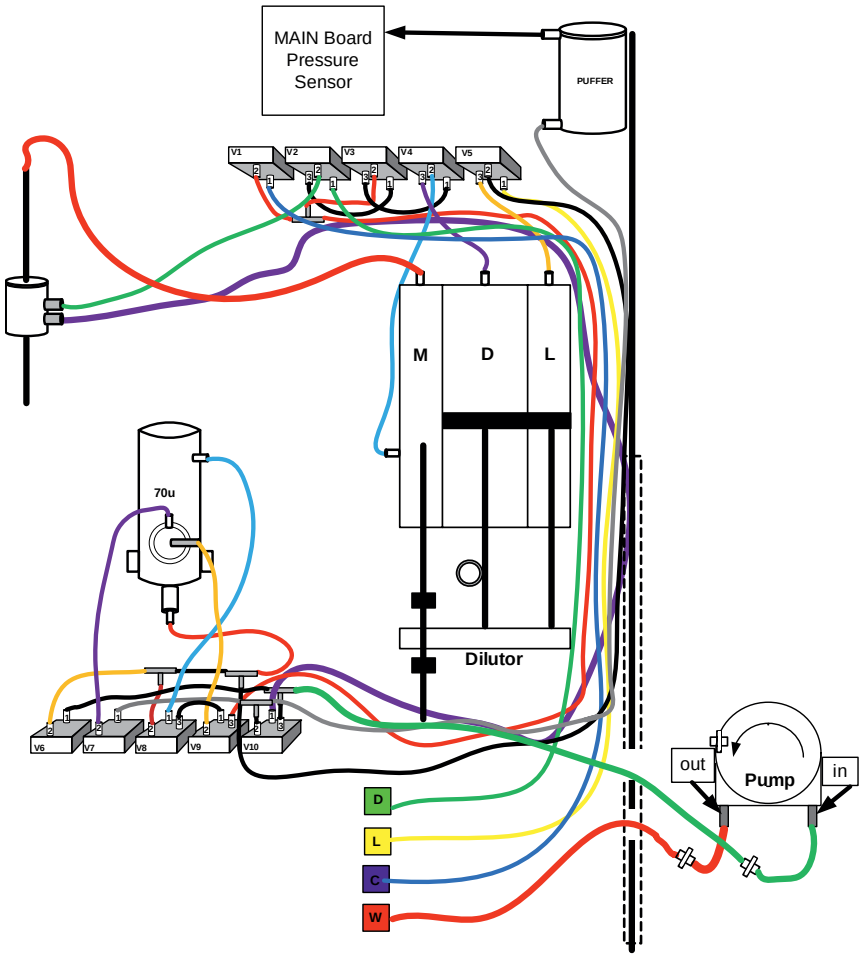
FIGURE 60

HC60[TS] cabling scheme

10.4 Tubing schematics

FIGURE 61

Tubing schematics HC30TS



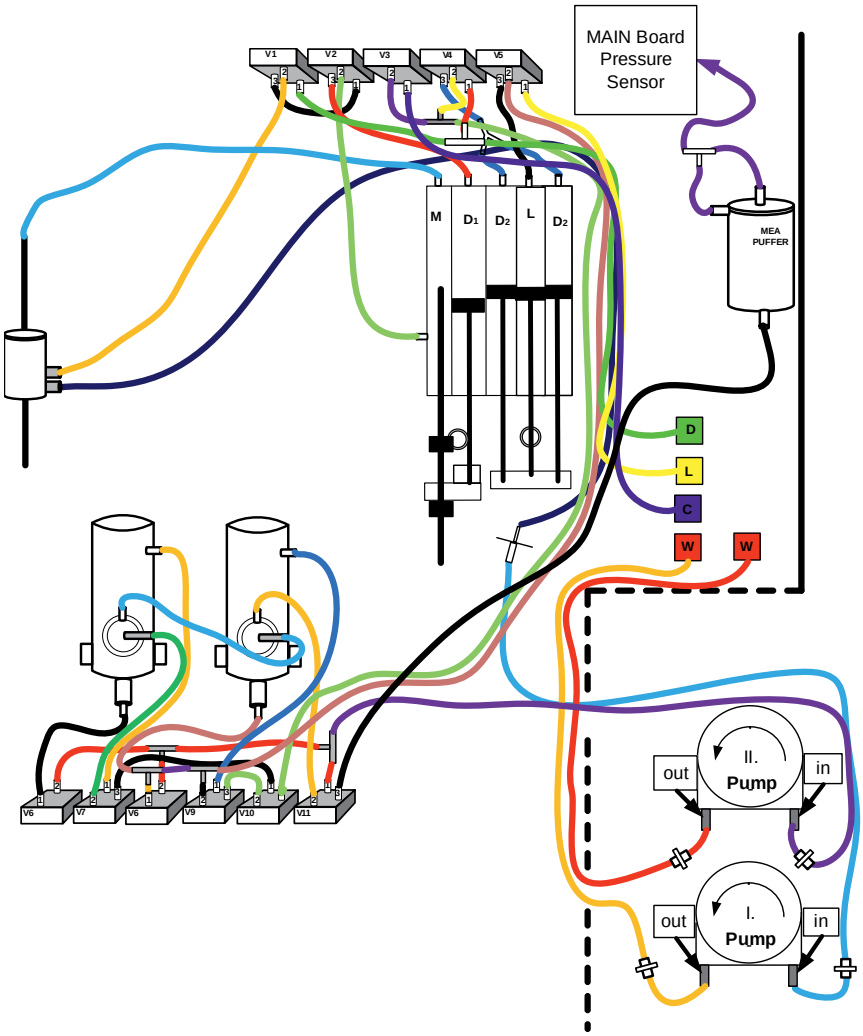


FIGURE 62

Tubing schematics HC60TS

10.5 Recommended kit of tools

- Screwdrivers:
  - Cross Slot Screwdrivers (Philips)
  - Slot Screwdrivers
  - Hexagon Screwdrivers (3.5, 2.5, 2.0, 1.5 mm sizes)
- Pocket digital multimeter
- Diagonal Cutter (plier)
- Nipper

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