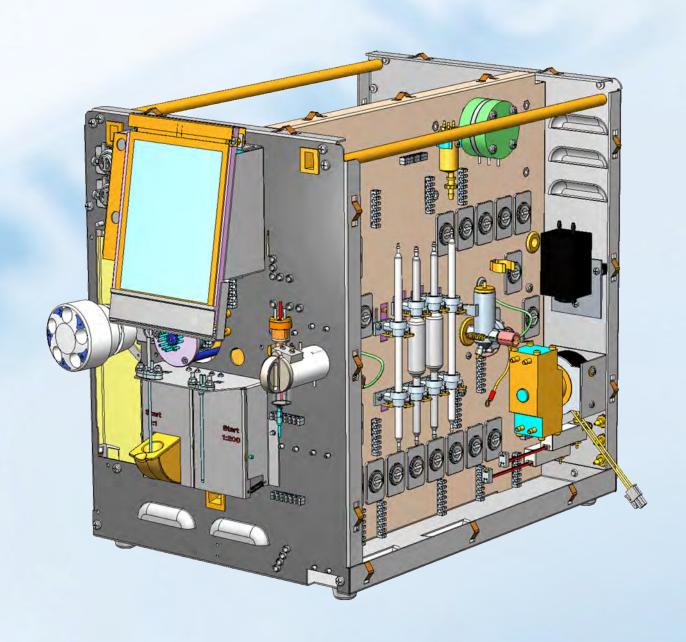
Boule Medical BM800



Service Manual

Medonic M-series
Swelab Alfa Instruments
Exigo Instruments



0. Quick guide to this service manual (V14)

Filed as first page

| | 1 Service manual issues, company guidelines (V05) | |
|--|---|-----------|
| <u>1,1</u> | Update checklist | |
| | How to use this manual | |
| 1,2 1,3 1,4 1,5 1,6 1,7 | Technical Service Guidelines. | |
| <u>1,4</u> | Returning of goods | |
| 1,5 | Tools required | |
| 1,6 | Knowledge required | |
| 1,7 | Copyright notice | |
| | 2 BM800 fluidic system principles (V06) | |
| <u>2,1</u> | <u>General</u> | |
| <u>2,2</u> | Symbol glossary (legends) | |
| <u>2,3</u> | Basic principle | |
| 2.3.1 | 1 Home position | |
| 2.3.2 | | |
| 2.3.3 | 3 First dilution | |
| 2.3.4 | 4 Sample transfer | |
| 2.3.5 | 5 Final dilution | |
| 2.3.6 | 6 Counting | |
| 2,4 2.4.1 2.4.2 2,5 2.5.1 | CAP/Sampler | |
| 2.4.1 | 1 CAP | |
| 2.4.2 | Sampling Device (Autosampler/Autoloader) | |
| 2,5 | Veterinary application | |
| 2.5.1 | 1 Unique component for Veterinary instruments | |
| | 3 Mains (line) power supply issues (V04) | |
| <u>3,1</u> | Mains Stabilizers | |
| 3,2 | Noise test menu | |
| | 4 Auxiliary devices (V03) | |
| <u>4,1</u> | Cap piercer (Optional for human instrument) | |
| 4.1.1 | | |
| 4.1.2 | | |
| 4.2 | Service maintenance for Cap piercer | |
| 4.2.1 | | |
| 4.2.2 | | |
| 4.2.3 | | |
| 4.2.4 | | |
| 4,3 | Auto sampler/Auto loader (Optional for human ins | strument) |
| 4.3.1 | | <u></u> |
| 4.3.2 | | |
| 4.4 | Service maintenance for Auto sampler | |
| 4.4 | | |
| 4.4 | | |
| 4.4 | | |
| | 5 Service menu explanation and use (V03) | |
| <u>5,1</u> | Clot Removal | |
| | Noise Test | |
| 5.3 | <u>Configuration</u> | |
| 5.4 | Pump & Valve | |
| 5,2 5,3 5,4 5,5 5,6 5,7 | Instrument log | |
| 5.6 | Flush shear valve | |
| 5.7 | Blood detector | |
| <u>5,7</u> <u>5,8</u> | Level detectors | |
| <u>5,0</u> <u>5,9</u> | Beaker detector | |
| 5.10. | Reagent detectors | |

| <u>5,11</u> | HGB picture display |
|---------------|---|
| <u>5,12</u> | Shear Valve |
| <u>5,13</u> | <u>Needle</u> |
| <u>5,14</u> | CVP |
| | Part replacement / Special procedures (V06) |
| <u>6,1</u> | Air pressure pump (P+) |
| 6,2 | Vacuum pump |
| 6.2.1 | Aspiration P-lower |
| 6.2.2 | Drain/Fill P-upper |
| 6.2.3 | Replace pump repir kit 1150521 |
| 6,3 | Changing PCBs |
| · | |
| <u>6.3.1</u> | CPU PCB Distribut DCB |
| <u>6.3.2</u> | Display PCB |
| <u>6.3.3</u> | Power supply |
| <u>6,4</u> | HGB adjust |
| <u>6.4.1</u> | HGB adjustment for a already installed board |
| <u>6.4.2</u> | HGB adjustment for new installed board |
| <u>6,5</u> | Mixing cup cleaning/adjust |
| <u>6,6</u> | Pipette and measure tube detector |
| <u>6.6.1</u> | Replacement of detectors |
| 6.6.2 | Replacement of glass pipettes |
| <u>6,7</u> | Replacement of shear valve |
| 6.7.1 | Replacement old model of shear valve 1090927_S |
| 6.7.2 | Replacement new model of shear valve 1091308_S |
| | ndications / error-codes (V05) |
| | Indications numbering |
| 7,1 7.2 | Indication Beep Pattern |
| | General (V03) |
| | Print All Settings (P.A.S.) |
| <u>8,1</u> | |
| 8,2 | Print Instrument Log (P.I.L.) |
| | nterface / Communication (V06) |
| 9,1 | Interface with USB CPU board |
| 9.1.1 | LIS interface |
| <u>9.1.2</u> | Printer interface |
| <u>9.1.3</u> | Barcode interface |
| 9.2 | Interface with non USB CPU board |
| <u>9.2.1</u> | RS232 serial cable configuration |
| 9.2.2 | Establish a connection with Hyper terminal |
| 9.2.3 | How to transfer patient results from BM800 instrument to file |
| 9.2.4 | Hyper terminal software upgrade |
| 9.2.5 | Problem solution during Hyper terminal upgrade |
| 9.3 | USB software upgrade |
| 9.4 | Problem solutions during USB upgrade |
| 9.4.1 | Downgrade to older version from USB memory stick |
| 9.4.2 | Step-by-step upgrade to newer version from USB memory stick |
| 9.4.3 | Recover from lost main board application |
| 9.4.4 | Recover from lost USB subsystem application |
| 9.4.5 | Recover from lost display board application |
| | General failure analysis (V02) |
| 10,1 | HGB and/or WBC instability |
| · | |
| <u>10,2</u> | MCV instability WRC instability |
| 10,3 | WBC instability |
| <u>10,4</u> | RBC instability |
| 10,5 | PLT instability |
| | Maintenance schedule (V06) |
| <u>11,1</u> | General schedule |
| <u>11,2</u> | Service protocol BM800 |
| <u>12</u> S | Schematics (V03) |
| 12 1 | PCB description |

Note that this service manual is "alive". Always check the Boule support site for udates and read section 1.1 and 1.2 first.

page 3/3 Section 0 Version 14

| <u>12.1.1</u> | PCB communication |
|---------------|---|
| <u>12.1.2</u> | CPU board |
| <u>12.1.3</u> | <u>CPU 00169</u> |
| <u>12.1.4</u> | Power supply 0235 |
| <u>12.1.5</u> | Display 00215 |
| <u>12.1.6</u> | Valve drivers 00204 |
| <u>12.1.7</u> | Level detectors 00323 |
| <u>12.1.8</u> | Cap piercing unit 01055 |
| <u>12.1.9</u> | Sampler unit 00975 |
| <u>13</u> | Spare part list (V09) |
| <u>14</u> | Troubleshooting and error guide (V02) |
| <u>14.1</u> | <u>Display issues</u> |
| <u>14.2</u> | Valve board and valve issues |
| <u>14.3</u> | Shear Valve and movement issues |
| <u>14.4</u> | DP and DF error flag |
| <u>14.5</u> | Aspiration failure AF flag OT and CT mode |
| <u>14.6</u> | High PLT with SE flag or DE flag |
| <u>14.7</u> | HGB related problem HL,HH and HF flag |
| <u>14.8</u> | TE flag |
| <u>14.9</u> | TU and TL flag for RBC and WBC |
| <u>15</u> | Bulletins (V01) |

| Boule | Page 1/13 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 1 Version 05 |

| 1. Se | rvice manual issues, company guidelines (V05) | 2 |
|-------|---|----|
| | Update checklist | |
| | How to use this manual | |
| 1.3 | Technical Service Guidelines. | 4 |
| 1.4 | Returning of goods | 9 |
| | Tools required | |
| 1.6 | Knowledge required | 12 |
| | Copyright notice | |
| | | |

1. Service manual issues, company guidelines (V05)

1.1 Update checklist

This section shows the history for manual updates; see section 0 for actual version of each section. Updates are available to download from support web pages..

*The first entry is an example only

| Date | Section | Version | From | Sign |
|--------------|---------|---------|--------------|------|
| *1 Aug 2005 | 2 | V 01 | Support site | BB |
| 22 Dec 2011 | 13 | V 08 | Support site | PL |
| 4 Jan 2012 | 0 | V 13 | Support site | PL |
| 4 Jan 2012 | 2 | V 06 | Support site | PL |
| 16 Jan 2012 | 6 | V 05 | Support site | PL |
| 19 Mars 2014 | 0 | V 14 | Support site | PL |
| 19 Mars 2014 | 1 | V 05 | Support site | PL |
| 19 Mars 2014 | 4 | V 03 | Support site | PL |
| 19 Mars 2014 | 5 | V 03 | Support site | PL |
| 19 Mars 2014 | 6 | V 06 | Support site | PL |
| 19 Mars 2014 | 7 | V 05 | Support site | PL |
| 19 Mars 2014 | 9 | V 06 | Support site | PL |
| 19 Mars 2014 | 11 | V 06 | Support site | PL |
| 19 Mars 2014 | 12 | V 03 | Support site | PL |
| 19 Mars 2014 | 13 | V 09 | Support site | PL |
| 19 Mars 2014 | 14 | V 02 | Support site | PL |
| | | | | |

1.2 How to use this manual

Not all sections or chapters should be learned and memorized. Sections as below recommend to be followed step by step during service/maintenance. Sections describing the basic operation of the instrument should be studied and memorized as well as general information regarding basic trouble shooting. Below template can be used as internal sign of, to check that service manual have been studied, understood and memorized.

| Section | Study and memorize | Reference only | Description | Sign |
|-----------------|--------------------|----------------|---------------------------------------|------|
| 1.1/1.2/1.3/1.6 | Yes | - | Manual issues / guidelines/copyright | |
| 1.4 /1.5/1.6 | - | Yes | Returning goods/ tools required | |
| 2 | Yes | - | Fluidic system description | |
| 3 | Yes | - | Mains (line) power issues | |
| 4 | | Yes | Aux devices | |
| 5 | | Yes | Service display picture explanation | |
| 6 | - | Yes | Changing parts / Special procedures | |
| 7 | - | Yes | Indications /error-codes | |
| 8 | - | Yes | Print settings / log | |
| 9 | - | Yes | Serial proto / upgrade software | |
| 10 | Yes | - | Parameter failure analysis | |
| 11 | - | Yes | Maintenance schedule | |
| 12 | - | Yes | Electronic diagrams | |
| 13 | - | Yes | Spare parts | |
| 14 | Yes | | Trouble shooting and error help guide | |
| 15 | - | Yes | Technical bulletins | |
| | | | | |
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1.3 Technical Service Guidelines.

Introduction

This section is a guide on how to implement a solid technical service department. Even if you as a distributor have an ISO certificate, the below guidelines might provide you with additional information on how to organize your staff to get maximum customer satisfaction and a fruitful business relationship with Boule.

Although the information provided in the document might be obvious for most readers, experience has shown that repeating obvious rules and guidelines never 'hurts' and is necessary to maintain an optimum level of customer satisfaction. Selling equipment and just waiting for a customer call is surely a way to get problems, less profit, higher staff turnover and general dissatisfaction. Further, it also must be clear that, "a problem that is not reported does not exist"

Instrumentation requires both maintenance and technical service. We will therefore make a distinct difference between maintenance and service. Also, it must be stated that maintenance and service begin with the sale and installation of the instrument.

Installation of the equipment

Before any form of maintenance is performed, the instrument must be installed exactly according to the specifications of Boule. If the installation specifications cannot be met, the problems/issues must be corrected before any use of the equipment can commence. Hence, it is the responsibility of the sales and technical service staff to check that the instrument is always working within the conditions/specifications set by the manufacturer Boule. Violating the conditions/specifications can result in:

- Excessive service
- Low Mean Time Between Failure, hereafter referred to as MTBF
- Poor customer satisfaction

It is the responsibility of the manufacturer Boule to specify the installation and working conditions for optimal performance. Likewise, it is the responsibility of the distributor and technical service department to check that these conditions are met not only at the installation of the instrument but also throughout the daily use of the equipment.

Training

Before an instrument is put in service at the end-user the instrument maintenance and end-user operation must be clarified. The equipment manufacturer Boule specifies:

- Sample handling
- Methodology of analysis and instrument limitations
- Use of controls and calibrators
- Maintenance schedule performed by the technical staff of the distributor
- End-user maintenance

It is extremely important that the end-user understand that proper sample collection and handling are vital for ease of use and accuracy of the instrument.

The above mentioned points must be clearly stated by Boule. As such, Boule must state:

- Regular maintenance: cleaning, basic testing of the equipment etc.
- How samples are handled and the consequences of not following such routines
- The limitations of the methodology and the instrument in providing correct data, e.g. extreme pathological cases and their influence on the collected data (results).

As distributors you should not rely on the idea that the end-user is familiar with the above mentioned points and follows procedures and routines. A much better approach is to start training and instruction as if there is no knowledge base. Having a solid training program available for both the user (or users) and the responsible head of the department will facilitate in a clear knowledge of the instrument beginning with installation.

Hence, the distributor sales and technical department must be fully aware of how to perform a detailed training program for the end-user. As such, the responsibilities are:

- 1. Organize instructional training for the user and let him or her perform tasks like daily and monthly maintenance.
- 2. Organize instructional training for the responsible head of the laboratory department and inform him or her about:
- Methods of sample collecting and their limitations
- The importance of using controls at regular intervals
- User maintenance as shown in the user manual
- Instrument possibilities and limitations on clinical data provided

It is of great importance that the above points are stated and if necessary repeated by the sales and/or technical staff of the distributor if it is noticed that the equipment is not being used according to the specifications stated by the manufacturer Boule. Typical cases of such might be:

- Incorrect mains power supply or accessory equipment connected to the device
- Incorrect sample handling
- Incorrect or insufficient end-user maintenance
- Failure to run quality control samples

One of the tasks of the distributor is to check and correct any abbreviation from the initial installation of the equipment. A database should be kept by the distributor, which includes a description of the type of instrument, installation date, responsible sales and service staff at this location and other necessary customer information.

Maintenance (user)

Maintenance is the key to success in any long-term sales. As with any other form of costly items like cars, the instrument needs regular hands on maintenance. Within the laboratory field, this mainly consists of cleaning and checking procedures. In certified laboratories, this includes a detailed list of actions that must be carried out at specified intervals. These items consist of but are not limited to: calibration, control procedures, reference checks, etc. In the event that the instrument is not located within such a controlled environment, it is the duty of the sales and technical staff of the distributor to provide the user with a detailed list of necessary maintenance steps.

The manufacture Boule is responsible to have such a detailed list clearly stated within the user manual.

The distributor is responsible to check that these guidelines are followed by the end-user.

How to 'SELL' maintenance?

Complete maintenance free equipment does not exist! Even if Boule states that maintenance is 'low', there is still some maintenance needed to facilitate in keeping:

- The MTBF as high as possible
- Minimize down-time
- Create maximum reliability of the clinical test results
- Create a maximum profitable environment for all parties

It is therefore important that at the sales-stage of the equipment the well-defined user maintenance is 'sold' as a protection of the equipment investment and not as 'negative' additional costs. Here is a task for the salesperson to sell not only just another_machine, but on the contrary a new customer for other products and services in the future.

Maintenance (distributor)

Maintenance and technical service are often closely connected to each other. We define maintenance performed by the distributor as: steps taken at regular intervals to increase the MTBF and keep unexpected services to a minimum.

The manufacturer Boule must state:

- Time intervals of such maintenance and/or dependency on the frequent use of the equipment
- Step by step approach to such maintenance
- Detailed description of parts that needs exchange within these periods.
- Continuous information must be supplied in form of bulletins, FAQ etc.
- Recommended stock of (spare) parts

The distributor must provide:

- Technical trained persons that are capable of performing disciplined tasks
- Regular training of the above force that checks and refreshes their capabilities
- Continuous corrections in their staff if necessary
- Distributing continuous information from Boule towards his service and/or sales staff.
- Database containing the installation, maintenance, and service records. Also included should be the name(s) of the person(s) in charge.

| Boule | Page 7/13 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 1 Version 05 |

The distributor's head of the technical department must regularly review this database for accuracy. Also required is for the technical department head to inform the instrument manufacturer Boule of 'glitches' or errors in their manuals, guidelines or other information provided. Such continuous flow of information and communication towards Boule might be in form of quarterly reports and/or statistics that describes clearly abbreviations from the Boule's instructions or parts that does not meet the expected MTBF.

It is the task of the distributor to keep track of all installed equipment, service staff involved, corrective actions needed at the end-user and/or service staff and keep the technical level at the sales and service staff up to date at all times.

Technical service organization topics

Following the above guidelines, the successful distributor should organize his technical sales staff as outlined below.

Head of technical service department

The head of the technical staff will be responsible for:

- 1. The technical level of his staff
- Checked by regular internal product examinations
- 2. The information flow provided by Boule and distribution of such to his staff.
- Service manuals must be inspected and checked that they are updated at all time
- 3. Check that the staff follows the guidelines from Boule
- Review service reports to insure they conform to the guidelines provided by the manufacturer Boule
- 4. Maintenance and service actions performed by his staff and statistics
- Check that service is done in a logical way and not just by 'cut and try'
- 5. Back reporting towards the manufacturer Boule
- Service/product MTBF statistics must be supplied to Boule at regular intervals
- 6. Taking decisions with his marketing department about renewals of end-user/customer training if found necessary.
- Check if service actions are caused by nonconformance or lack of user-maintenance of the equipment

Depending on the size of the distributor and/or local environment, the technical staff might be divided into sub units with each a responsible group manager which reports directly to the head of the technical service. It will be the group manager's responsibility to insure proper and current training of the staff.

Having regular meetings, (e.g. monthly) to review technical levels and maintenance/service disciplines will insure that the service group managers have maximum confidence in the equipment, their staff and services provided.

| Boule | Page 9/13 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 1 Version 05 |

1.4 Returning of goods

Returning of defective goods and warranty claims must apply to the procedures as outlined by Boule. Please refer to the enclosed procedure sheet and follow this step by step whenever returning goods to the manufacturer Boule.



REGISTRATION FORM FOR RETURN SHIPMENTS

Dear Distributor:

To return goods to Boule Medical please note the following:

- Return shipments that are not first approved by Boule Medical will not be accepted and will be returned at the distributor's expense.
- Return shipments that are not correctly registered or labeled may not be accepted and can be returned to Distributor at their expense.
- Freight and insurance of return shipment is to be arranged by Distributor at own cost.
- If defective parts are not returned to Boule Medical AB within 60 days, the replacement shipment will be invoiced according to pricelist.

Return shipping is made on distributor's responsibility and any items should be properly packed for export

Shipping instructions:

Keep cool

Original Boule order-/ invoice number: Reason for return:

ESD-package yes

To return the goods the enclosed form MUST accompany the goods back.

| | snipment and insured for dama | ages. |
|---|--|--|
| • | Shipments from outside EU co "Value 100 SEK for customs | ommunity must come with a Proforma Invoice stating value of shipment as suse only." |
| • | stated below. If none of these | so contain a H-S number for each returned article for customs registration as numbers fit the items you are to send back please refer to invoice of act order@boule.se for assistance. H-S 90278017 H-S 90279050 H-S 38220000 H-S 30029090 |
| • | Special conditions required: | |

no 🗌

| CLAIM NO: | Return shipment to: | | |
|-----------------------------|--------------------------|--|--|
| | Boule Medical AB | | |
| Distributor Name: | Attn: | | |
| Contact name/telephone no.: | Västberga Allé 32 | | |
| Product name | SE-126 30 Hägersten | | |
| Article no returned: | Sweden Sweden | | |
| Quantity: | Tel. no. +46 8 744 77 00 | | |
| Serial no. (if applicable): | | | |
| Lot no. (if applicable): | | | |

yes 🔲

no

1.5 Tools required

The BM800 is designed according to the metric system. Hence; bolds, nuts etc. are using metric standards e.g. M3, M4 etc.

Specialized tools are not necessary during service and/or fault finding. Be sure however that the following is available:

- 1. Digital Pressure/Vacuum meter . Range 0 to 900mBar / 0 to + 900mBar . Resolution: 1mBar *
- 2. Digital voltmeter. Range 0-10mV to 0-200V
- * The digital manometer is used for air-pressure/vacuum only and should be able to measure relative (differential) pressure/vacuum. Some typical models are shown below:



Figure 1.1 AV-Instrument Corp Model 8215



Figure 1.2 ASF-Thomas Model VDM 300 R

Note:

This pressure/vacuum meter can not be purchase through Boule but is recommended to have as a service tool, this to save time and make sure that pumps and pneumatic system works well in BM800 system. Recommendation would be to search on internet or try to find similar pressure/vacuum meters locally for best price.

| Boule | Page12/13 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 1 Version 05 |

1.6 Knowledge required

Boule assumes that the reader and qualified service technician has at least the following knowledge and experiences:

- 1. Basic knowledge about fluidic systems (e.g. clinical chemistry analyzers and/or hematology analyzers or similar)
- 2. Basic knowledge and use of different tube materials like: PVC/Tygon, Silicon, Polyethen, PTFE(Teflon)
- 3. Knowledge of service disciplines in general
- 4. Complete knowledge of the user-manual
- 5. Basic knowledge of physical and electrical units and the ability to interpret measured results.
- 6. Safety guidelines & procedures regarding blood-and waste products

1.7 Copyright notice

PLEASE NOTE:

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This copy issued by :

Date :

Boule Medical AB

Västberga Allé 32 SE-126 30 Hägersten Sweden

| 2. BM800 |) fluidic system principles (V06) | 2 |
|----------------------------|---|----|
| | neral | |
| 2.2 Sy | mbol glossary (legends) | 3 |
| • | sic principle | |
| 2.3.1 | Home position | |
| 2.3.2 | Aspiration | |
| 2.3.3 | First dilution | 15 |
| 2.3.4 | Sample transfer | 16 |
| 2.3.5 | Final dilution | 17 |
| 2.3.6 | Counting | 18 |
| 2.4 CA | .P/Sampler | 19 |
| 2.4.1 | CAP | 19 |
| 2.4.2 | Sampling Device (Autosampler/Autoloader) | |
| 2.5 Veterinary application | | 21 |
| 2.5.1 | Unique component for Veterinary instruments | |
| | | |

2. BM800 fluidic system principles (V06)

2.1 General

This chapter explains, in brief (excluding the washing and cleaning steps), the fluidic system of the BM800. The reader needs to understand the components and their use in the analyzer.

The BM800 performs two dilutions, 1:400 and 1:40,000. The 1:400 dilution is used for the WBC and HGB determination and the 1:40,000 dilution is used to perform the RBC and PLT measurements. These dilutions are done in 2 separate stages. The first and second dilution stages are completely separated from each other. One shear valve is used with 2 separated micro channels of 22.5 ul each.

Figure 2.1 shows the complete fluidic diagram with the BM800 in its home (idle) position. To understand it's functions in the diagram, please refer first to the symbol glossary below.

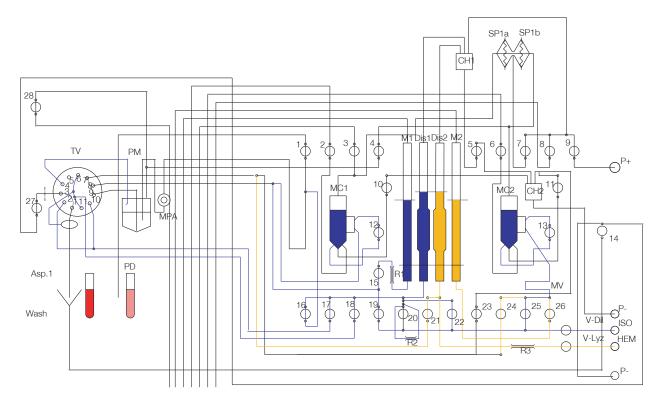


Figure 2.1

2.2 Symbol glossary (legends)

Referring to Figure 2.1, the following legends are used in the diagram:

ASP

The aspiration needle, which consists of a Teflon® tube within a stainless steel pipe.

Wash

Aspiration pipette washing device which is used to drain the cleaning fluid from the aspiration pipette.

PD (Only for human instrument)

Inlet for pre-diluted samples. Also used as a system vent and dispensing outlet.

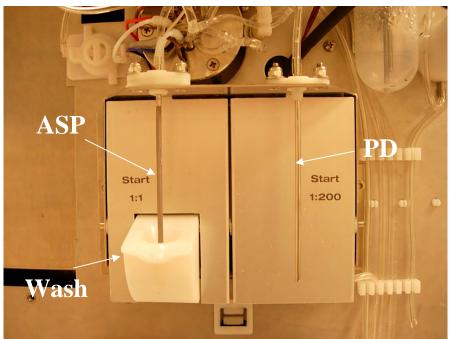


Figure 2.2

Shear Valve (SV)

Shear valve. The shear valve has two micro channels of each 22.5 ul. One channel is used for whole blood aspiration only where as the second one is used exclusively for diluted blood. In the home (idle) position, the first micro channel connects position 1 and 3 and the second channel connects position 7 and 9. The shear valve rotates, during the diluting process, clockwise and counter clockwise.

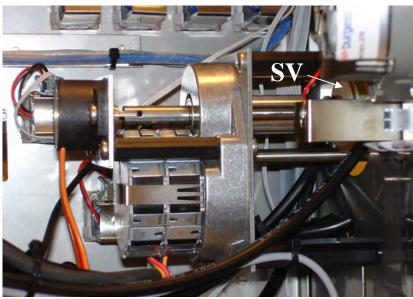


Figure 2.3

PM

The first dilution from whole blood is transferred to this primary mixing chamber. Hence, this chamber is used for the first 1:200 dilution to be mixed well before the diluted sample is split into the final 1:40,000 and 1:400 dilutions.



Figure 2.4

SP1a-SP1b

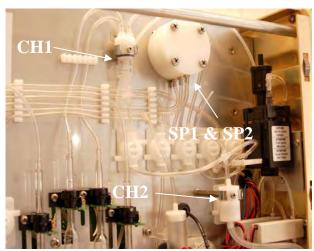
Air buffer membrane pump. This device is a passive pump. Two separate chambers containing 2 membranes (SP1a and SP1b) are used to buffer and release air-pressure. This pump is exclusively used during the counting process to pressurize the chambers MC1 and MC2.

CH1-CH2

Buffer chambers.

CH1 is used as a vacuum and pressure buffer.

CH2 is used as a waste buffer and filter for vacuum pump protection.



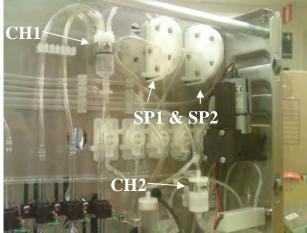


Figure 2.5 old version membrane pump

Figure 2.5.1 new version membrane pump

MC1

Measuring Chamber for the 1:40,000 dilution. Used for RBC and PLT parameter determination.

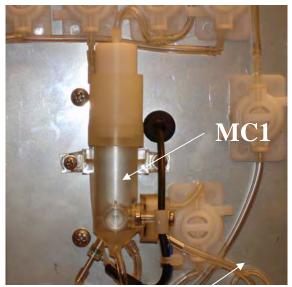


Figure 2.6

MC2

Counting chamber for the 1:400 dilution. Used for WBC parameter determination. This counting chamber contains the HGB photometer system as well.

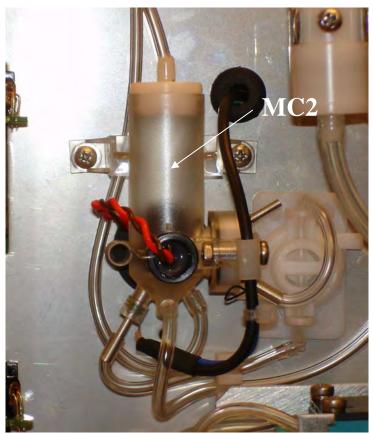


Figure 2.7

DIS1

Glass 4.5 ml pipette, containing start (lower) and stop (upper) optical detectors. This pipette is used for the first dilution (1:200) and the secondary 1:200 dilution, resulting in a 1:40,000 (1:200 x 1:200) RBC/PLT dilution. Note that this pipette only contains isotonic diluent.

DIS2

Glass 4.5 ml pipette, containing start (lower) and stop (upper) optical detectors. This pipette is used for the second and final WBC/HGB dilution (1:400). Note that this pipette only contains lyse.

M1 - M2

Metering units for the RBC/PLT [M1] and WBC [M2] measurements. These glass pipettes have fixed start (lower) and stop (upper) optical detectors, factory set at 270 ul each.

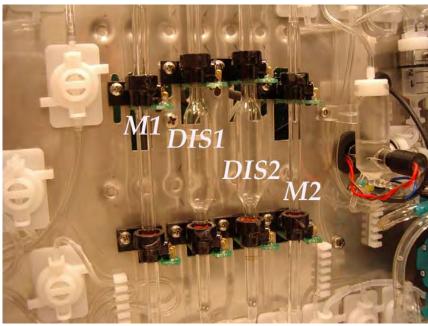


Figure 2.8

R1, R2 and R3

Restrictors. This tubing, which is located below the pipettes, are factory fixed restrictors having a fixed diameter dimension and length used to reduce pressure and/or flow speed (not visible in pictures).

MV

Factory volume calibrated Teflon® or polyethen tube set at 1.9 ml. This volume is used to create the 1:400 WBC/HGB dilution.

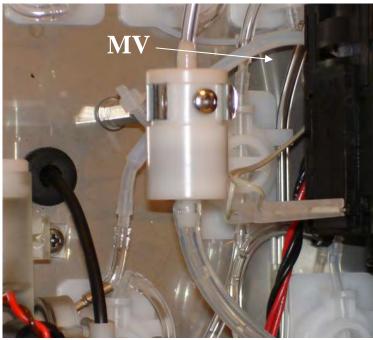
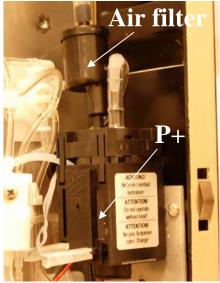


Figure 2.9

P+

Air pump, used only to supply pressure to dispense liquid from the DIS1-DIS2 pipettes (dilution steps) and to 'load' the passive pumps SP1a-SP1b. The right picture shows an air pump model introduced during 2007.



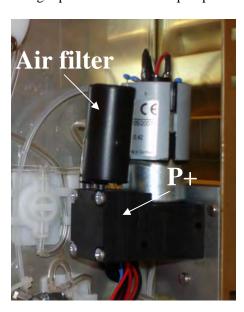


Figure 2.10

P-

A vacuum pump with two separate chambers. Hence 2 identical vacuum ports are available. The pump is used for blood aspiration, waste, emptying/filling pipettes, emptying/filling counting chambers and to move the liquid/dilution through the tubing.

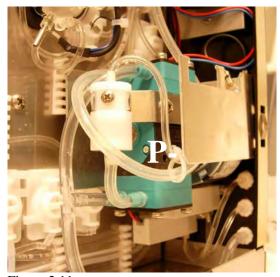


Figure 2.11

Service mandar Biviovo Boe

Valves

Valves are indicated as round numbered symbols. Bi-stable operation of the valves is used. Hence, no continuous power is supplied. Opening and closing a valve is performed by an electrical pulse which is either positive or negative. Refer to Figure 2.12.

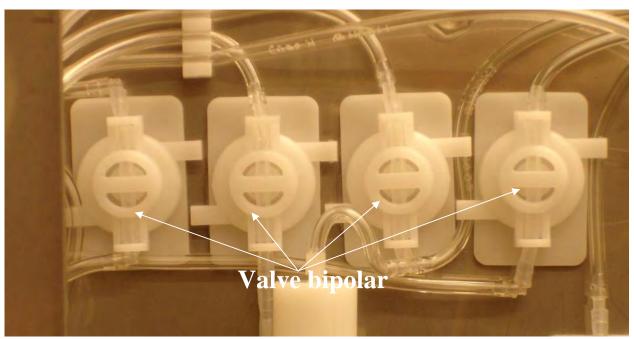


Figure 2.12

Bipolar Valve position for Human standard instrument

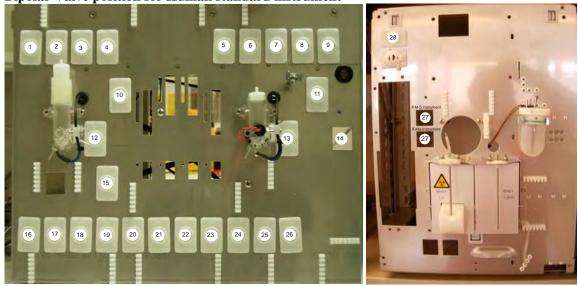


Figure 2.13 Figure 2.13A

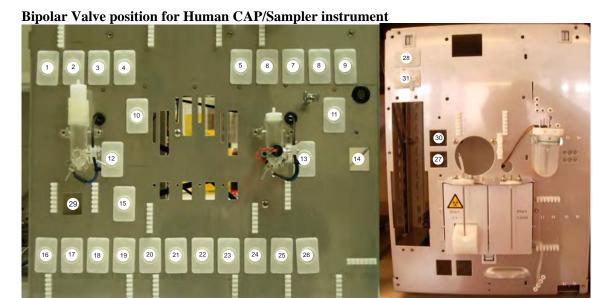


Figure 2.14 Figure 2.14A

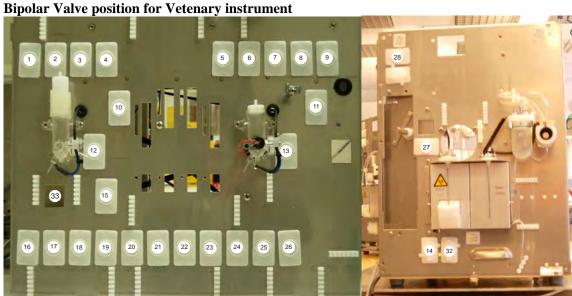


Figure 2.15A Figure 2.15

Vdil - Vlyz

Two valves at the diluent and lyse inlet are monostable. When the system is in normal power-off or standby mode, all Bi-stable valves release and are in open position. The two inlet valves will remain closed to prevent liquid flowing backwards into the diluent and lyse containers. Refer to Figure 2.16 and 2.16A. Figure 2.16A shows the new position of inlet valves introduced during 2008.

Veterinary instruments have two additional monostable valves which prevent Enzymatic cleaner to flow backwards into the enzymatic cleaner container. Refer to Figure 2.27.

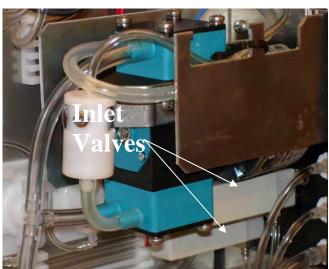




Figure 2.16 Figure 2.16A

There are five different blood inlets in the instrument: OT (Open Tube), MPA (Micro Pipette Capillary Device), PD (Pre-diluted), CAP (Cap Piercer), and AS (Sampling Device). All inlets are optional, except OT. The basic principal for counting is exactly the same for all five inlets. The difference is how and from which inlet the blood enters the mixing beaker. From the step where the blood is in the mixing beaker there is no difference between the different inlets. (See open tube (OT) example below.)

2.3 Basic principle

In Figure 2.17 below, the basic principle of the diluting and counting process is shown. For simplicity, 2 x 4.5 diluent pipettes and 2 shear valves are shown. Physically, only 2 x 4.5 ml pipette and one shear valve are used in the system.

- 1. Blood is aspirated through the shear valve with a vacuum created by the waste pump, see Figure 2.11.
- 2. The blood flow through the shear valve is stopped by a 'blood sensor'.
- 3. The shear valve turns to the diluting position and 4.5 ml of diluent from the pipette presses 22.5 ul of trapped blood into the mixing beaker, which creates a dilution of 1:200.
- 4. The vacuum of the waste pump forces the diluted sample in the mixing beaker through the shear valve and the precise teflon tubing of 1.9 ml (V1-V2) towards the WBC/HGB measuring chamber.
- 5. This flow is stopped by means of a sensor when approximately 0.5 ml is left in the mixing beaker. Hence, the (V1-V2) tube is now filled with the 1:200 diluted sample. Excessive sample dilution is eliminated through the waste pump. Also, the shear valve contains 22.5 ul of the diluted 1:200 sample.
- 6. The shear valve turns to position 'secondary dilution' and 4.5 ml of diluent from the pipette creates the final dilution ratio of 1:40,000 in the RBC measuring chamber.
- 7. Simultaneously, 4.5 ml of lyse from the lyse pipette presses the volume trapped in the (V1-V2) tube into the WBC/HGB measuring chamber giving the final dilution of 1:400.

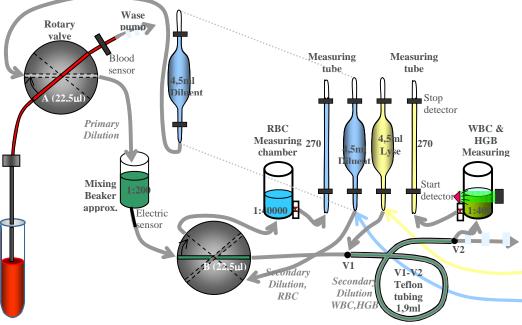


Figure 2.17

8. Pressure, supplied by SP1a-SP1b (see Figure 2.5), on top of the counting chambers RBC and WBC will press the sample through the orifices into the metering tubes. A start and stop detector gives a precise counting volume of 270ul.

| Boule | Page13/23 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 2 Version 06 |

2.3.1 Home position

In Figure 2.18, the analyzer is shown in its home position. The measuring cups MC1 and MC2 are partly filled with reagents. The primary mixing cup is empty and the shear valve SV is in its home position with pos. 1-3 and 7-9 connected via the micro channels. Any pressure is absent in chambers PM, CH1, CH2, SP1, MC1 and MC2. Pipettes and metering units are filled with diluent and lyse just above the stop detectors.

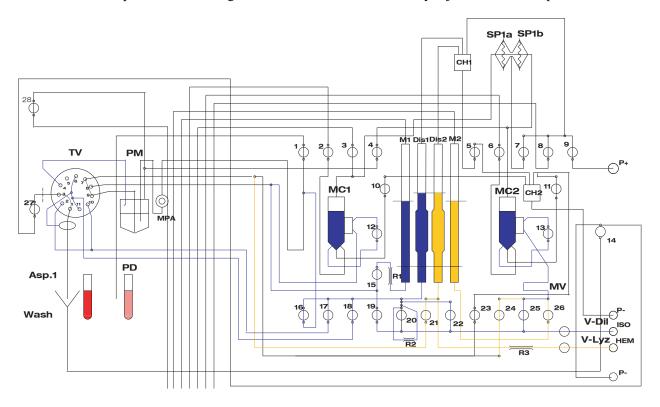


Figure 2.18

2.3.2 Aspiration

Sample aspiration, shown in Figure 2.19 is performed by a vacuum supplied through P- and opening V27 and V14 as bypass. The end of aspiration is detected by electrical conductivity between position 1 and 3 of the shear valve SV. Hence, aspirating distilled water will not be detected and a 10 second time-out will force the analyzer to continue the cycle.

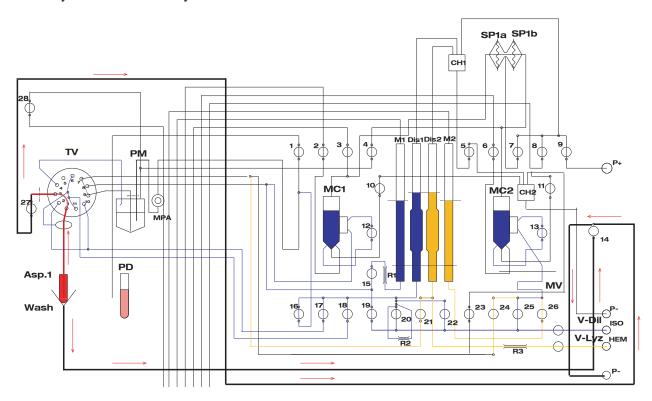


Figure 2.19

| Boule | Page15/23 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 2 Version 06 |

2.3.3 First dilution

The first dilution, shown in Figure 2.20 below, is done in the following steps:

- 1. The shear valve SV turns clockwise with the micro channel including the sample between position 2 and 4.
- 2. Pressure is supplied through P+ and V9 on top of the diluent pipette DIS1.
- 3. Valve 17 is opened and the diluent pipette DIS1 is emptied, with the sample in the micro channel, to the start detector of DIS1 into the mixing cup PM.
- 4. At the same time both measuring chambers will be sucked empty. V10, V3, V11, and V6 open allowing the vacuum pump to completely empty the chambers.

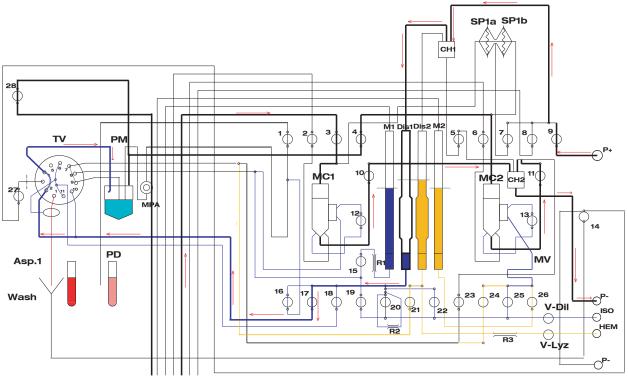


Figure 2.20

| Boule | Page16/23 | |
|-----------------------------------|----------------------|--|
| Service manual BM800 Doc No 01959 | Section 2 Version 06 | |

2.3.4 Sample transfer

The first dilution of the sample is now transferred towards MC2 using the following steps:

- 1. The metering units M1 and M2 are set to the lower position (start detector) via R1, V15, V12, V26, MV and V13.
- 2. The shear valve SV is turned to pos. 7-9 and V24 and V13 are open.
- 3. The pre-diluted sample now flows into MC2 and then flushed into the drain via V11.
- 4. The sample transfer is stopped by closing V24 when the lower detector is reached in PM. So, the volume MV (1.9 ml) is now filled with the pre-diluted sample.

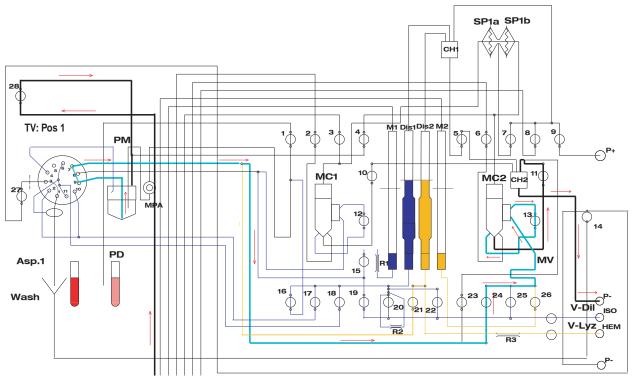


Figure 2.21

| Boule | Page17/23 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 2 Version 06 |

2.3.5 Final dilution

The final dilution for the RBC and WBC channel is described below:

The lyse DIS2 and diluent DIS1 pipettes are emptied simultaneously. DIS1 through V17, shear valve separation unit position 8-10 (which contains 22.5 ul of the diluted sample) and V12 into MC1. DIS2 presses the lyse through the volume MV into MC2, achieving a 1:1 dilution with the trapped sample in MV.

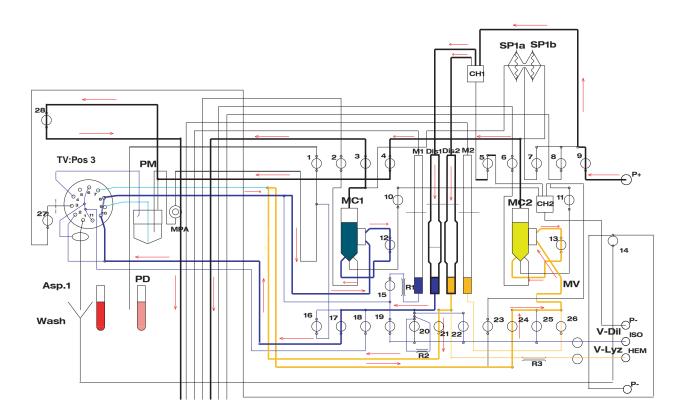


Figure 2.22

2.3.6 Counting

The counting of the sample is performed by applying a pressure on top of the sample(s) in chambers MC1 and MC2. This pressure is supplied by the air membrane pumps SP1a and SP1b. The common chamber of SP1a-b is prepared for counting by P+, V7 and V9.

The WBC counting is started by opening V26 and the RBC counting by V15. The dilutions are pressed through the orifices and the analyzing process ends when the stop detectors are reached in the metering units. The HGB is measured simultaneously in MC2. Note that a HGB blank measurement is done at the start of the blood aspiration for each sample. Hence, after the counting process, the HGB is calculated using a 'new' blank for each sample, eliminating the influence of any possible light intensity drift.

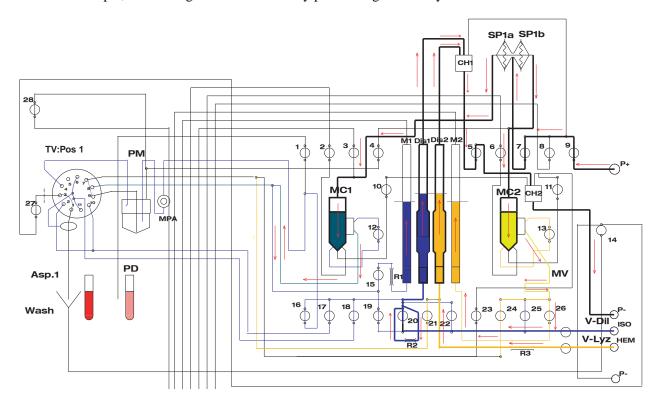


Figure 2.23

| Boule | Page19/23 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 2 Version 06 |

2.4 CAP/Sampler

2.4.1 CAP

When the door to the Cap Piercing device closes and a blood tube is detected, the needle starts to move upward and penetrate the tube. It is important that a tube filled with blood is inserted, if not the needle will not start to move upward. Note a tube with transparent liquid will not activate the motor for the needle. When the needle starts to move upward it will lock the door to the Cap Piercer, the door will not be able to open when the needle is in the upper position.

When the needle has penetrated the tube cap, blood will be sucked into the first channel of shear valve which is between pipe 5 and 3 with the suction of vacuum pump P-. When the blood passes the blood sensor, V27 will close and stop the suction of blood. From that point on the counting principal is the same as mentioned above.

Valves 29, 30, and 31 will only appear on the instruments with the optional CAP or Sampling Device.

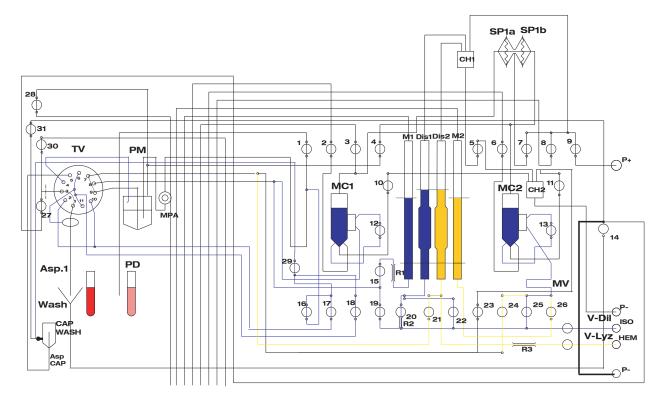


Figure 2.24

Service manual BM800 Doc No 01959

2.4.2 Sampling Device (Autosampler/Autoloader)

When a wheel has been mounted on the first wheel position, there are two options prior to the start of counting: One minute mix or an extra mix (1 to 15 minutes), before the first needle penetration and aspiration of blood. During the mixing, the detector will identify the position of the tubes and also the wheel number. There can be stored up to four different wheels with 20 positions on each of the wheels. The positions are determined with infrared detectors. When the mixing is completed the wheel will stop on the lowest tube filled position and the needle will move upward and penetrate the tube. When the needle moves upward it will also lock the wheel. When the needle has penetrated the tube cap, blood will be aspirated through the shear valve and channel one, which is connected between pipe 5 and 3, with vacuum pump P-. From that point on the counting principal is the same as mentioned above.

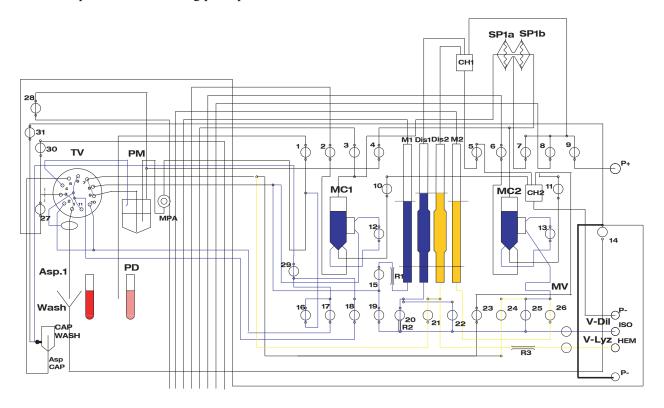


Figure 2.25

| Boule | Page21/23 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 2 Version 06 |

2.5 Veterinary application

The veterinary instrument differentiates from the standard human instrument by the extra cleaning reagent which fills the instrument in standby and power off cycles. This is done to prevent contamination and protein buildup in instrument's tubing.

The veterinary instrument has two additional inlet valves (monostable) to prevent cleaner from flowing back into the cleaner container and two extra bi-stable valves for control of liquid movement in the system.

The veterinary instrument does not have a PD (Pre-dilute) inlet, but the inlet tube is used for air flow.

Exigo Eos 19 parameters has one extra dilution pipette which is used for eos reagent.

Also three extra inlet valves and one bi-stable valve are added in the Eos model compared to standard Exigo, see figure 2.27 and 2.32

Exigo 17 parameters:

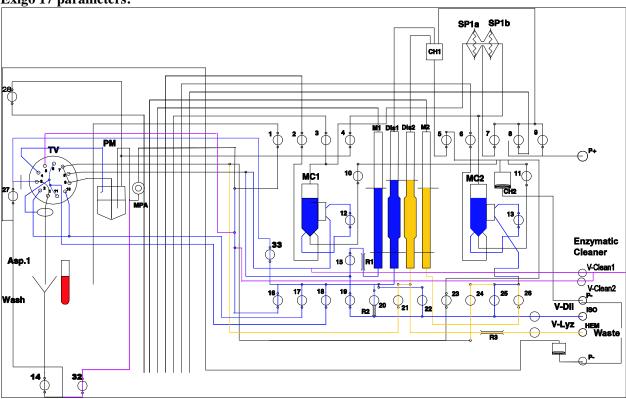


Figure 2.26

Exigo Eos 19 parameters:

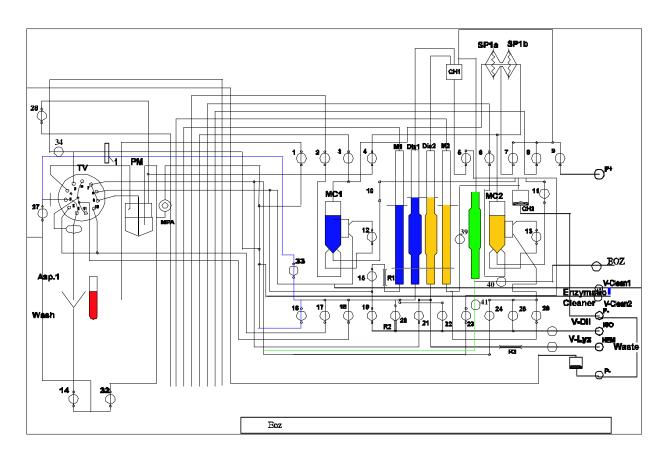


Figure 2.27

2.5.1 Unique component for Veterinary instruments

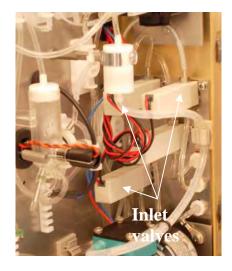




Figure 2.28 Inlet valves

Figure 2.29 Start plate



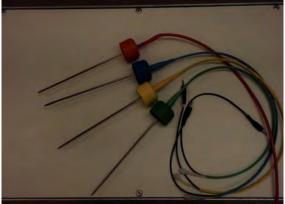
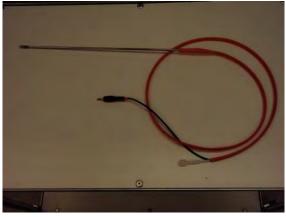


Figure 2.30 Reagent tray

Figure 2.31 Reagent detectors



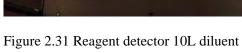




Figure 2.32 Eos pipette with extra inlet valves

| Boule | Page 1/4 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 3 Version 04 |

| 3. | Ma | ins (line) power supply issues (V04) | 2 |
|----|----|--------------------------------------|---|
| | | Mains Stabilizers | |
| | | Noise test menu | |

3. Mains (line) power supply issues (V04)

3.1 Mains Stabilizers

The BM800 is equipped with a line input filter that suppresses noise in the low-frequency region (10-200 KHz).

If the BM800 is used in areas with highly unstable mains supplies or if a high risk for mains-power surges caused by lightning exists, it is recommended to use an additional line-stabilizer.

The choice of the mains-stabilizer is an important issue.

In general the only acceptable stabilizer type is a so-called 'Magnetic Stabilizer', also named CVT (Constant Voltage Transformer) or 'Ferro-Resonant Transformer'. This type consists mainly of a large transformer run into saturation. The output voltage is than filtered, usually by large capacitors and coils, to obtain a sinusoidal voltage. (max. distortion 5 %)

These stabilizer types are common, old fashioned, rugged, without moving parts and cheap. However they do not supply battery backup in case of a total mains power failure, which in most cases is not necessary.

(An UPS [Uninterruptible Power Supply] can be used, hence during some circumstances a CVT is recommended)

Using this type of stabilizer, it is important that the ground system of the BM800 is not disturbed. Below, an example is given on how to connect the BM800 with all accessories and keep the ground system intact. As seen, it is essential that the grounding of the system is at one point (the stabilizer). This setup reduces the risk of 'ground-loops' which might cause interference and /or damage the BM800.

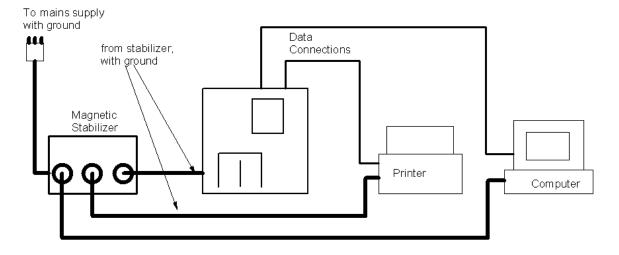


Figure 3.1

In case you are not familiar with CVT devices or need to buy this item locally, please enter the following text in your internet search engine: CVT constant voltage transformer

3.2 Noise test menu

In addition to the above, the BM800 has a built-in 'Noise Test' menu which basically measures signals at the orifice electrodes when no cells are passing through the orifice and without any current supplied to the electrodes.

Enter this 'Noise Test' from the service menu.

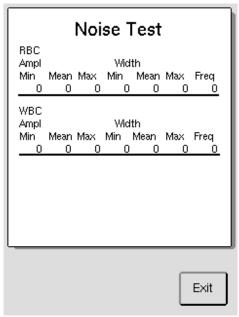


Figure 3.2

The values shown must be zero '0' at all times or not more than some short 'bursts' with low numerical values are acceptable.

In case *steady* numerical values are shown > 0, a possible mains (line) interference might be the source.

The discriminator and filter settings are used to determine at which amplitude the noise is present. The shown default values are the same as running a normal sample or blank. Lowering the discriminator values gives a hint if there is noise present below the default discriminator level, which might cause interference with the measurements under 'hard' conditions.

A typical line interference is shown to the user as a sharp size distribution curve which is either found on PLT (most likely), RBC or WBC. See example in Figure 3.3 below.

| Boule | Page 4/4 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 3 Version 04 |

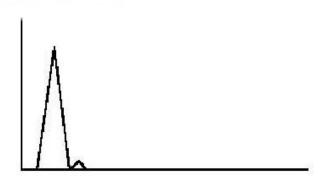


Figure 3.3

In general:

In case of suspected line-interference, use a CVT to correct the problem and check/inspect the grounding system of the equipment and laboratory.

If you are not familiar with CVT type of stabilizers, please enter your Internet search engine with the phrase 'CVT constant voltage transformer' to get more detailed information about purchasing such locally. Power requirements for a suitable CVT must be > 150VA.

| 4. | Auxıl | hary devices (V03) | 2 |
|----|---------|---|----|
| | | piercer | |
| | | Cap piercer aspiration failure | |
| | 4.1.2 | Replace the needle | 4 |
| 4 | | vice maintenance for Cap piercer | |
| | | Remove CT needle for cleaning purpose | |
| | 4.2.2 | Remove wash cup for check/replacement | 5 |
| | 4.2.3 | Replace Cap aspiration tubing | 6 |
| | 4.2.4 | Clean and grease Cap mechanic | 7 |
| 4 | | to sampler/Auto loader | |
| | 4.3.1 | Aspiration failure | 9 |
| | | Replace the needle | |
| 4 | 4.4 Ser | vice maintenance for Auto sampler/Auto loader | 10 |
| | 4.4.1 | Remove CT needle for cleaning purpose | 10 |
| | 4.4.2 | Replace Sampler aspiration tubing | 11 |
| | 4.4.3 | Clean and grease needle mechanic | 11 |

4. Auxiliary devices (V03)

This chapter describes how to service Cap and Sampler devices. Most common problems with close tube are that rubber particles from sample tube caps are stuck in aspiration line like, needle, tubing or shear valve. Section 4 together with 14 describes how to dismount parts and solve issues related to closed tube device.

4.1 Cap piercer

By using the Cap piercing device, direct contact with blood can be avoided. The Cap device demands three extra monostable valves compared to standard instruments. The Cap piercing device has three different optical sensors. Two are used for detecting the lower and upper position for needle. The third one is used as tube detector (see Figure 4.2). This sensor check that a tube with at least 1ml blood is present; otherwise cap piercer will not start. If customer would like to analyze a sample tube with diluent or hypochlorite inside then some mark like tape etc. must be put on the tube, close to the cap.



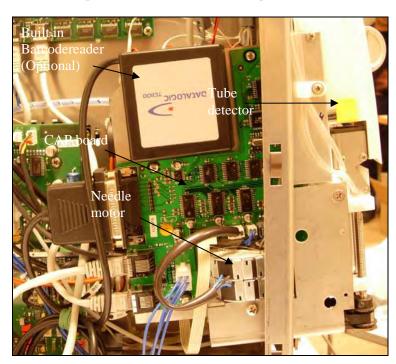


Figure 4.2

Figure 4.1

The detectors can manually be controlled by select [NEEDLE] from the [SERVICE] menu (See Figure 4.3) [Needle menu is protected with service password 3819]. By choosing [UP] and [DOWN] the needle will be moved to the upper and lower position and the 'Top' and 'Bottom' status will change from 0 to 1. (Note: It is very important that the door to the Cap Piercer is either closed or completely open (See figure 4.5) when the needle test is performed. If the door is not in one of these positions, the needle could become bent.

To completely open the Cap piercer door, loose the screw which holds the CAP door from inside of instrument (see Figure 4.4) and move door to the position seen in Figure 4.5.

The Cap Piercer door has it own micro switch to detect a closed or open door (See Figure 4.5). If the door switch and the tube detector are activated at the same time the needle will start to move up and penetration will occur. (This is not valid when in the test display [NEEDLE], the needle is able to move up and down even if the door switch or tube detector are not activated. Make sure to not move the needle if the door is in the normal open position.)

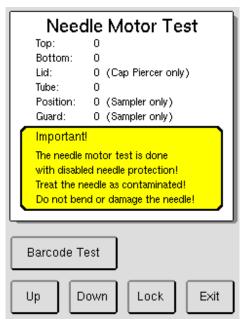
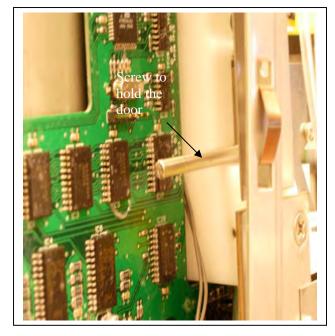


Figure 4.3



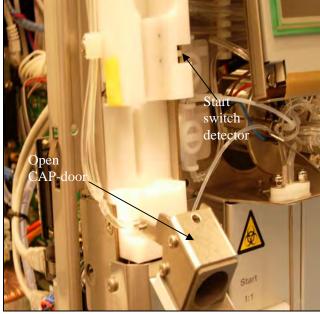


Figure 4.4 Figure 4.5

4.1.1 Cap piercer aspiration failure

If aspiration is not possible, clots or rubber from the tube cap might be blocking aspiration line. To clean the needle follow the previous description and move the needle to the upper position, detach the Teflon tube from the lower part of the needle. To make sure if the blockage is in the needle, attach an air filled syringe to the lower part of the needle and make sure there is air flow, if not run a thin (<1.0mm) metal wire up and down through the needle to remove any blood/rubber clots inside the needle. If there is still no air flow, remove the needle as in 4.1.2 and try to flush it through with diluent or hypochlorite as described in 4.2.1

If the aspiration failure is caused by a blockage in the Teflon tube, remove and replace the Teflon tube. Make sure to put the silicon tube on the Teflon tube and to mount the Teflon tube all the way into Pipe 5 on the shear valve, it might affect the instrument functionality if this is not done correctly.

4.1.2 Replace the needle

If needle needs to be replaced detach the silicon/Teflon tube from the needle, remove the upper locking washer (see Figure 4.6) from the needle, and pull the needle down. There is an O-ring which seals needle vs wash cup, make sure not to damage the o-ring. Press the new needle through the opening in the plastic holder and up through the Wash cup O-ring, make sure that a new lower retaining ring is mounted on the needle before pressing it through the plastic holder. Mount the upper locking washer back on the needle to fix it in place.

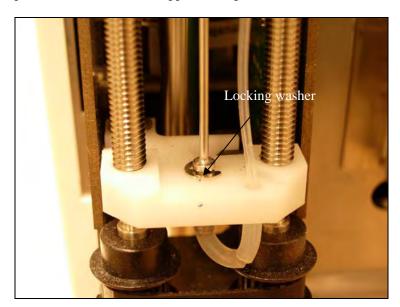


Figure 4.6

4.2 Service maintenance for Cap piercer

During yearly PM Service, Boule recommends to check some sensitive parts for the closed tube aspiration module. Cleaning of needle, wash cup and aspiration tubing would be recommended together with cleaning and greasing of mechanical parts.

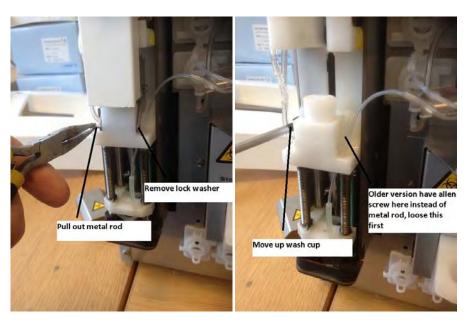
4.2.1 Remove CT needle for cleaning purpose

Remove the needle as described in 4.1.2. Connect a syringe with 2% Hypochlorite and flush back and forward to see and feel if there some obstruction inside the needle. Let the needle be filled with Hypochlorite for 15 min and then try to flush again to see if some more particles comes out of from the needle, see photo below. Note!! Treat this procedure as Biohazard and use gloves etc.



4.2.2 Remove wash cup for check/replacement

After 1 year or more it is recommended to check/replace 1021055_S wash cup for Cap needle. Cap needle is moving through an O-ring which is present inside the wash cup. This O-ring can not be replaced separately and if it has worn out the complete wash cup needs to be replaced. In later version of cap modules, the wash cup is fixed with a metal rod and locking washer, in older version there is a small allen screw which holds the wash cup from right side.





Replace this wash cup if needed, in later version we have implemented a lid on top of wash cup. This lid prevents that liquid can leak down to optical sensors on Cap board.

4.2.3 Replace Cap aspiration tubing

As aspiration tubing (1091171_S) moves up and down together with needle during analyze, we recommend looking over this tube during yearly maintenance. It is very sensitive if this tube gets pinched or partial blocked as aspiration and washing will be insufficient and next sample result will probably not be ok. After each analyze this tube should be washed and dried out automatically. In case some blood or liquid can be visual in this tube after a sample cycle then clean the needle or complete aspiration line through shear valve. 1091171_S, Cap aspiration tubing is made from 9970119 Teflon tubing, length for this tubing should be 19cm. Protection tubing outside Teflon tubing is made from 4.5 cm of 9970001 Silicon tubing.



| Boule | Page 7/11 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 4 Version 03 |

4.2.4 Clean and grease Cap mechanic

During service maintenance we recommend to clean and grease the Cap mechanic. This as the power to puncture the rubber cap in a sample tube is rather high.

Clean the metal rods and grease them with Silicon/Teflon lubricant.

After cleaning and greasing, move the needle up and down from Service menu 2- Needle to make sure that the movement works ok.



4.3 Auto sampler/Auto loader

The Sampling Device is used to prevent direct contact with blood and it gives the opportunity for the operator to analyze 20 samples as a walk away system and not need to be close the instrument. Two different wheels can be loaded with 20 samples each (see Figure 4.7), one wheel will perform analyses while the other wheel is mixing and preparing for analysis. If interference happens with the wheel movement during the rotation of the wheel the process will be stopped and a warning screen will be displayed.

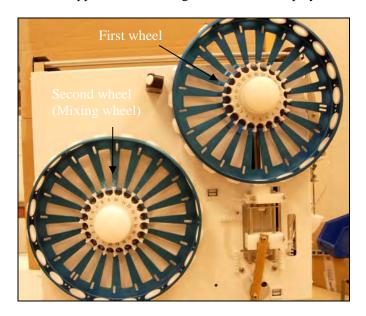


Figure 4.7

The Sampling Device has two detectors (see Figure 4.8), one to detect the tube and one to detect the tube position on the wheel.

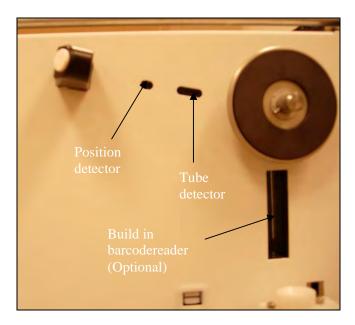


Figure 4.8

The detectors can be tested from the [NEEDLE] in the [SERVICE] menu [Needle menu is protected with service password 3819]

The needle movement for the Sampling Device can be tested in the same way as the Cap Piercer (see Figure 4.3).

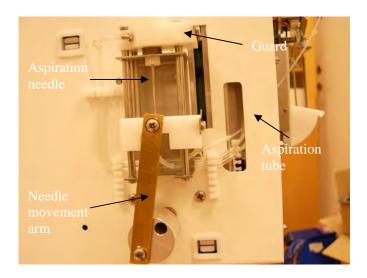


Figure 4.9

4.3.1 Aspiration failure

See Section 4.1.1 Cap piercer aspiration failure and 4.4 for likely cause

4.3.2 Replace the needle

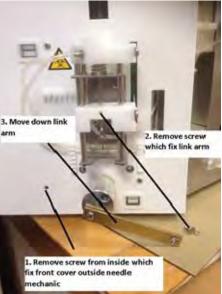
Unscrew the upper screw on the needle movement arm. Detach the silicon/Teflon tube from the needle. Unscrew the needle from its holder (see Figure 4.9). When the complete needle body is unscrewed, pull the needle down, and remove it. Mount the new needle back into the needle holder body and tight the screw.

4.4 Service maintenance for Auto sampler/Auto loader

During yearly PM Service, Boule recommends to check some sensitive parts for the closed tube aspiration module. Cleaning of needle and aspiration tubing would be recommended together with cleaning and greasing of some mechanical parts.

4.4.1 Remove CT needle for cleaning purpose





- 1. Remove front cover for sampler, one screw fix the cover from inside of sampler door
- 2. Loose the screw to link arm and move it down to reach the needle.
- 3. Needle is fixed in plastic thread, remove the tubing and unscrew needle with plier or 7 mm key.
- 4. Remove the needle. Connect a syringe with 2% Hypochlorite and flush back and forward to see and feel if there some obstruction inside the needle. Let the needle be filled with Hypochlorite for 15 min and then try to flush again to see if some parts come out of the needle, see photo below.

 Note!! Treat this procedure as Biohazard and use gloves etc.



4.4.2 Replace Sampler aspiration tubing

During service maintenance, we recommend looking over sampler aspiration tube. It is very sensitive if this tube gets pinched or partial blocked as aspiration and washing will be insufficient and next sample result will probably not be ok. After each sample analyze this tube should be washed and dried out automatically. In case some blood or liquid can be visual in this tube after a sample cycle, recommendation would be to clean needle or complete aspiration line through shear valve. 1091192_S, sampler aspiration tubing is made from 9970119 teflon tubing. Length for this tubing should be 30 cm.



4.4.3 Clean and grease needle mechanic

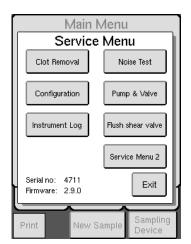
During service maintenance we also recommend to clean and grease needle mechanic. Loose the screw for the link arm and manually move the white house to end position and then clean and grease the rods. Silicon/Teflon lubricant would be recommended. Mount link arm back and check needle movement up and down from Service menu 2-Needle.

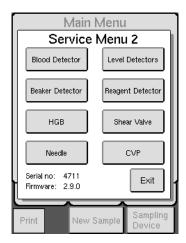


| 5. Service menu explanation and use (V03) | 2 |
|---|---|
| 5.1 Clot Removal | |
| 5.2 Noise Test | 2 |
| 5.3 Configuration | |
| 5.4 Pump & Valve | |
| 5.5 Instrument log | 3 |
| 5.6 Flush shear valve | |
| 5.7 Blood detector | 4 |
| 5.8 Level detectors | |
| 5.9 Beaker detector | 5 |
| 5.10 Reagent detectors | 5 |
| 5.11 HGB picture display | 6 |
| 5.12 Shear Valve | |
| 5.13 Needle | 6 |
| 5.14 CVP | 6 |
| | |

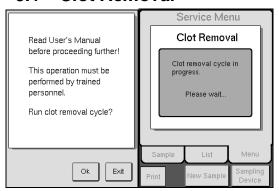
5. Service menu explanation and use (V03)

From Menu-Advanced-Service menu we can find options to test and verify that parts inside the instruments works properly. Also some adjustments can be performed from here. See below to understand what option that is available.





5.1 Clot Removal



See user manual appendix A for more explanations. This function can be used to manually back flush aspiration channel on shear valve between pipe 1 and pipe 3 with a syringe. Waste pump will drain the wash bin below OT needle in the same as syringe is manual pressed to remove possible clot.

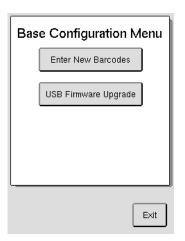
5.2 Noise Test



Noise test can be checked during installation and troubleshooting for high PLT and WBC background.

Note. instrument must be filled with reagent to have correct information from screen, values should be close to 0. Sometimes a small fluctuation from RBC channel can be seen and this is nothing that should affect the result. See Section 3 in Service menu for further explanations.

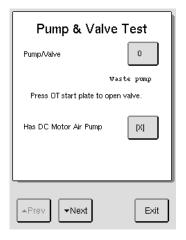
5.3 Configuration



Configuration will be used in case an instrument configuration change is requested. For example: 16 parameter instruments can be updated to 20 parameter from this menu. This can be done after scanning a barcode sheet from Boule.

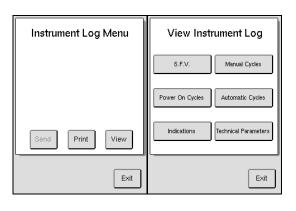
USB firmware upgrade is used for software upgrade, see section 9.3

5.4 Pump & Valve



By choosing a valve number and press the start plate behind Open tube needle, the chosen valve can be activated. The chose can either be done by click [Next] until the correct valve is displayed or press on the valve number area and type the correct valve number to select it. Waste pump (0), Air pump (42) and Inlet valves can also be tested from this menu.

5.5 Instrument log



The Instrument Log describes the instrument's activities.

S.F.V (Sub board Firmware Version): states the software versions of all boards.

Manual Cycles: states all manual/operator made cycles.

Power on cycles: states the latest power on cycles, manual and automatic.

Automatic cycles: states the latest instrument activated cycles.

Indications: states the latest indications that occurred (see Section 7 for more information).

Technical parameters: states different technical instrument parameters (see Section 8 for more information).

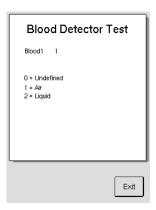
Section 5 Version 03

5.6 Flush shear valve



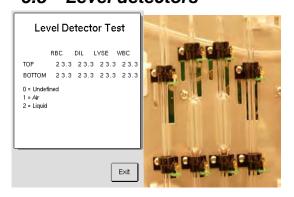
During activation of Flush shear valve cycle, the instrument will automatically try to back flush aspiration channel with diluent and in same time move the shear valve mechanic back and forward. This procedure can in some cases solve an Indication 71 and 75 issue if shear valve is stuck or there is a small blockage inside aspiration channel

5.7 Blood detector



The shear valve has two blood (liquid) detectors. Both are electrical conductive detectors, one for the Open tube inlet and the other for the Cap/sampler device. When diluent is pressed through the aspiration channel in shear valve a beep should appear. Detector status change from 1 to 2. This to understand that blood detector signal works ok.

5.8 Level detectors



Level detectors for the four glass pipettes are fixed at a default measured volume. This volume may not be changed in anyway, see Section 6 for replacement. When the liquid reach the detector, the signal will change from 1(air) to 2(liquid). Status for empty will be displayed 1.0.1 (1=Air and 0.1V). Status for filled will be displayed 2.3.3 (2=liquid and 3.3V)

In case '0' is displayed the detector can not determine if it is liquid or air, it might be that the glass needs to be rotated manually so it finds the correct level (rare occasions)

5.9 Beaker detector

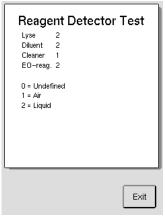


The beaker detector is a conductive sensor and detects the difference between liquid and air inside mixing beaker. When the mixing beaker will be filled with first dilution, the two metal pipes with spring cable on top will be connected. The beaker status then switches to 2 (liquid). During the preparation of second dilution, first dilution will move out of beaker until liquid level reach higher detector. Then beaker status will change to 1(air). This is how instrument controls level of second dilution and empty of premix cup.

5.10 Reagent detectors



Human instrument



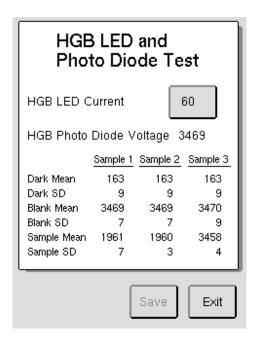
Vet Eos instrument

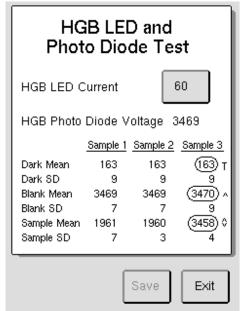
The reagent detectors/probes which are present in the reagent containers are a conductive sensor. Each detector has a cable connection which should be mounted to correct connector on the backside of CPU board. Status for these detectors can be checked.

When reagent probe is present inside reagent container, status 2(liquid) should be present on display. When reagent probe is removed from container and no liquid is detected, status 1(air) should appear. Waste detector is not in use today.

Note. Numbers of reagent cycles during barcode of reagent containers has no relation to reagent detectors. It is two separate things.

5.11 HGB picture display





Figures 5.10 a and b

HGB menu displays the status from the photo diode and detector inside WBC chamber. Photometer has a working range between 3200-3800 where the target value should be 3500. This can be adjusted as in section 6.4

Information about three latest analyzed samples is displayed from HGB menu.

For example: Sample 1:

Blank mean: 3469; this is the light photo detector see during blank measurement on ...

diluent.

Sample mean: 1961; this is the light photo detector see during sample measurement on

diluted blood

HGB result will be displayed based on the difference between Blank and Sample mean.

Blank mean value is higher: 3469 then Sample mean: 1961, this as the light scattering from diluent is less then from sample and more light from diode reach photo detector

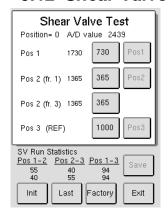
#: Stability of the readings [Values ≤ 50 = stable; > 50 = unstable]

Background example:

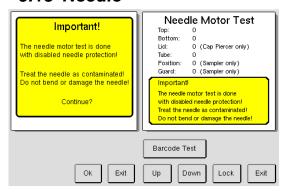
T: Dark value range 160-180
This is the value detector see when diode is switched off

- ^: Blank readings. It should be about the same as HGB photo diode voltage. (Unless there is a problem with the liquid flow)
- Sample reading. The background analysis should be the same as HGB photo diode voltage.

5.12 Shear Valve



5.13 Needle



Each instrument and shear valve module has it own specific settings (displayed values are only an example)

Init: To perform an initialization of the shear valve.

Last: Return to the last saved shear valve setting.

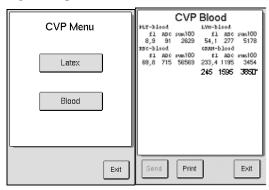
Factory: Return to the picture as displayed (Should never be used).

Pos1, Pos2 and Pos3 move the shear valve to it fixed position. These position are related to different steps in the analyze cycle, see flow diagram in section 2 to understand when which position is used. See Section 6 in service menu for further explanations.

From this menu Closed tube needle mechanic (Cap/sampler) can be moved up and down. Also possible to check sensor position for needle/tube/Lid/wheel together with internal barcode function

See Section 4 for further explanation.

5.14 CVP



After replacement of CPU board or WBC orifice, a CVP check with Boule control is recommended. Correct gran peak value from latest control blood lot can be received from Boule up on request. The displayed GRAN blood in CVP from latest Boule normal control run should match the recommended value with +/-15fl. See section 14.11 for more information.

| 5. | Part | replacement / Special procedures (V06) | 2 |
|----|-------|--|----|
| | | Air pressure pump (P+) | |
| 6 | | Vacuum pump | |
| | 6.2.1 | | |
| | 6.2.2 | 1 | |
| | 6.2.3 | * * | |
| 6 | 5.3 | Changing PCBs | |
| | 6.3.1 | | |
| | 6.3.2 | 2 Display PCB | 9 |
| | 6.3.3 | | |
| 6 | 5.4 | HGB adjust | 9 |
| | 6.4.1 | HGB adjustment for a already installed board | 9 |
| | 6.4.2 | | |
| 6 | 5.5 | Mixing cup cleaning/adjust | |
| 6 | 5.6 | Pipette and measure tube detector | 11 |
| | 6.6.1 | Replacement of detectors | 12 |
| | 6.6.2 | Replacement of glass pipettes | 12 |
| 6 | 5.7 | Replacement of shear valve | |
| | 6.7.1 | Replacement old model of shear valve 1090927_S | 13 |
| | 6.7.2 | | |

6. Part replacement / Special procedures (V06)

During replacement and test of spare parts in BM800 follow procedures step by step as below. Special procedures listed in this section are usually 'called' from a service or maintenance sheet and should be followed step by step. Do not memorize these procedures as they might change with new application software or manual updates. However, the reader of this manual should be aware that such procedures exists and that they should be followed whenever referred to from other sections in service manual or other BM800 related manuals.

6.1 Air pressure pump (P+)

Procedure:

1. Locate the air pressure pump (P+) and connection tube marked as P+ in Figure 6.1 below.

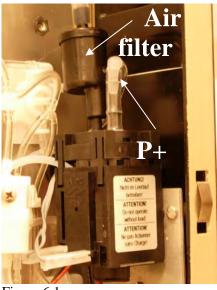




Figure 6.1

- 2. Connect the digital vacuum/pressure meter at the (+) outlet.
- 3. Go to the Service Menu and select [Pump & Valve]. Press [NEXT] until [42. Air pump] is displayed.
- 4. Activate the air pump by continually press the start plate and read pressure displayed on meter.
- 5. The pressure limits are: 250-700mBar, a normal air pump should be around 500mbar
- 6. If the pressure is lower than 250mBar the air pump must be replaced

6.2 Vacuum pump

Vacuum pump/motor has 2 separate membrane houses. The lower part is used for blood aspiration and draining the needle washing device. The upper part is used for filling and emptying the chambers/glass pipettes (Dis1, Dis2) etc.

6.2.1 Aspiration P-lower

Aspiration P-lower is used for the aspiration of blood and for drying the inlet needle. If both RBC and HGB parameters are not reproducible or there is a failure in the aspiration of blood, measure the suction on the P-lower.

Procedure:

1. Locate the vacuum pump (P-lower) and connection the tube marked as '*' in Figure 6.2.

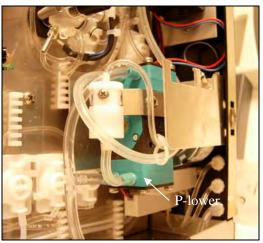






Figure 6.2

- 2. Connect the digital vacuum/pressure meter at the suction connector
- 3. Choose Service Menu and select the [Pump & Valve] button. Select 'Waste-pump' [0]
- 4. Press and hold start plate behind OT needle to activate the pump and read the vacuum displayed on the meter.
- 5. The vacuum limits are: 500-900mBar.
- 6. If the vacuum is lower than 500mBar, start by cleaning the pump membranes and valves. If the problem persists replace the pump membranes, see section 6.2.3.
- 7. If the pump is in need of cleaning, follow the procedure as in 6.2.3, unscrew the four screws that hold the membrane together, lift carefully both parts from the pump body. Lift the top part.. Clean the two membranes and also the big round membrane. Make sure when remounting the membranes on the pump body that the ridges on the membrane match the ridges on the plastic body, and that the flat membrane area matches the flat part of the plastic body.
 - Do not over tight the four screws on top of the pump house during mounting
- 8. In case problem persist, replace the pump repair kit, see 6.2.3 below.
- 9. When waste pump is mounted back, make sure ground cable is mounted properly. This so pump is correct grounded vs back chassis. Otherwise high WBC result with DE flag can appear

6.2.2 Drain/Fill P-upper

The upper part is used for filling/emptying the chambers/glass pipettes (Dis1 and Dis 2) together with moving liquid in and out of the system.

Procedure:

1. Locate the vacuum pump (P-upper) and connection tube marked as '*'(Suction) in Figure 6.3 below.

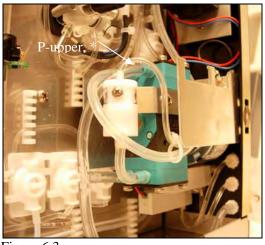






Figure 6.3

- 2. Connect the digital vacuum/pressure meter to the suction outlet.
- 3. Choose Service Menu and select the [Pump & Valve] button. Select [Waste-pump 0].
- 4. Press and hold start plate behind OT needle to activate the pump and read the vacuum displayed on the meter.
- 5. The vacuum limits are: 500-900mBar.
- 6. If the vacuum is lower than 500mBar, the pump membranes in the housing must be cleaned or replaced.

6.2.3 Replace pump repair kit 1150521

In case capacity for upper or lower part is still low after cleaning, then we recommend replacing this kit. During replacement use protective glows and treat this as biohazard material.

After 2-3 years use, we recommend replacing this kit in PM Service.







6.3 Changing PCBs

Some of the PCBs need to be checked / adjusted after replacement, follow procedure below. During replacement for all electronically boards we recommend to make sure that you are properly grounded. To prevent electrostatic discharge we strongly suggest the use of an ESD-bracelet connected to ground. If procedure is not strictly followed, secondary errors might be introduced.



6.3.1 CPU board

The CPU PCB has several ICs that store specific instrument information, user setups and statistics. These ICs are not a spare part that can be ordered they are transferred from the 'old' PCB to the 'new' PCB to maintain the instrument type and status. Therefore, the 'old' PCB must be at hand whenever changing the CPU PCB. Refer to Section 12 for detailed information.

Procedure:

- 1. Go to Setup menu and select [Print All Settings] (P.A.S.)*
- 2. Go to Service menu and select [Print Instrument Log] (P.I.L.) and print.
- 3. Switch off the BM800 and demount the CPU PCB.
- 4. Remove **IC34** (see figure 6.5) from the 'old' PCB and insert in the same position (IC34) on the 'new' PCB.
- 5. Remove **IC35** (see figure 6.5) from the 'old' PCB and insert in the same position (IC35) on the 'new' PCB.
- 6. Remove IC36 from the 'old' PCB and insert in the same position (IC36) on the 'new' PCB. (Most models have no IC36 inserted, cancel this point in such a case), See section 12 for IC34-36 position.
- 7. Check that Jumper J2 is in place (connected).
- 8. Mount the 'new' CPU PCB into the BM800.
- 9. Connect the cables according to the Figure 6.4.
- 10. Switch on the BM800.
- 11. The BM800 will display Indications. Check Section 7 for explanations.
- 12. The BM800 might ask to confirm the setup of the EEPROM or RAM. Choose *always* EEPROM (=**EE**). Or the BM800 might display an indication number saying that the contents in the RAM are lost, if so, just continue.
- 13. Go to Setup menu and select [Print All Settings].
- 14. Check that #1 and #13 above are identical regarding setup parameters. Special attention is required on the shear valve calibration settings. If not change the setup so it matches the original PAS.
- 15. Go to Maintenance menu and run a [Prime Cycle] or [Fill system] if required to put the fluidic pathway back in order.
- 16. Connect a mV meter between P30-1 and P30-2 and adjust RV2 for 0.0mV reading. See Fig 6.5
- 17. Connect a mV meter between P30-3 and P30-2 and adjust RV1 for 0.0mV reading. See Fig 6.5.
- 18. Go to the instruction on how to set the HGB blank reference range. (See Section 6.4)
- 19. Reset the calibration constants for all parameters back to '0'.
- 20. Run a Boule calibrator/control and check that the MCV is within 5% from the target value. If not, adjust RV4 (see Figure 6.5) and rerun the control until it is ok.
- 21. Run a Boule control and check that the WBC GRAN-mode (the Granulocyte peak volume) is within 10 fl from the target value (the target value has been established from another BM800 and though it might vary from batch to batch it is constant within a batch). The value can be displayed from the [CVP] button in the Service menu. If the GRAN-mode is not within the above tolerance range, adjust RV3 and rerun the control until it is ok. See Figure 6.5.
- 22. Calibrate and check the BM800 using a Boule calibrator and controls.
- 23. Repack the 'old' defective CPU PCB and note in detail the failure description.

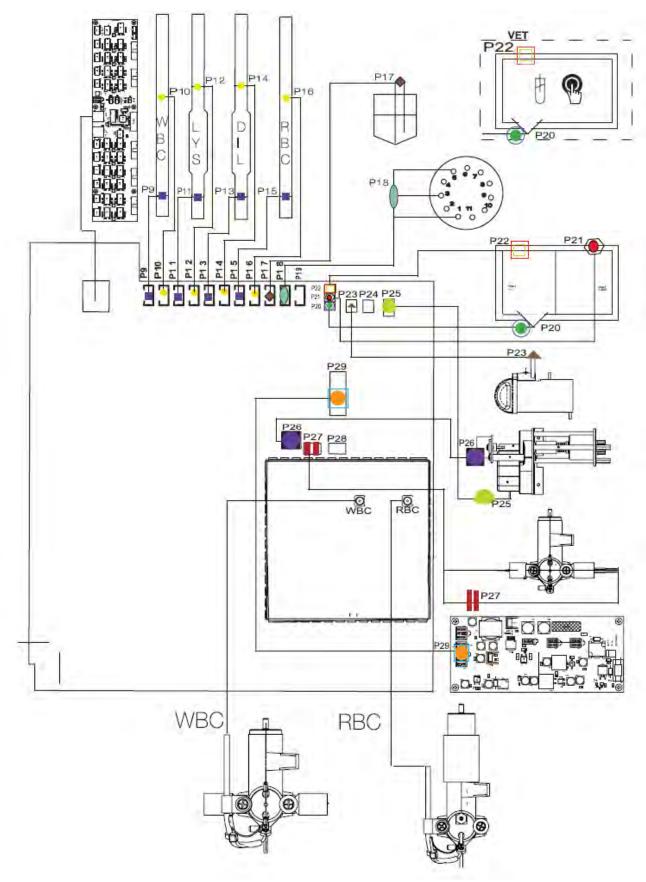


Figure 6.4

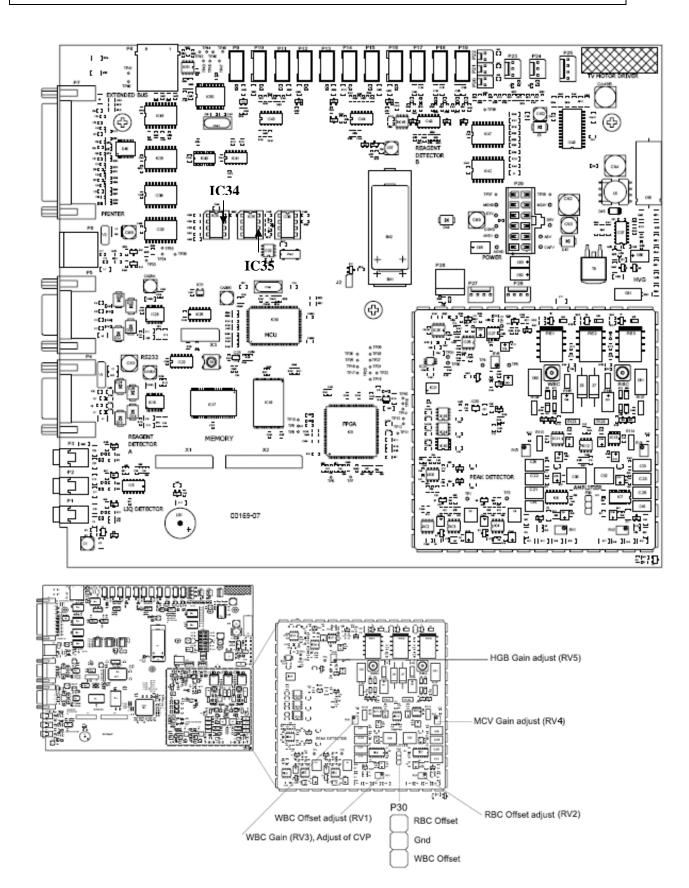


Figure 6.5 Older version of USB CPU board

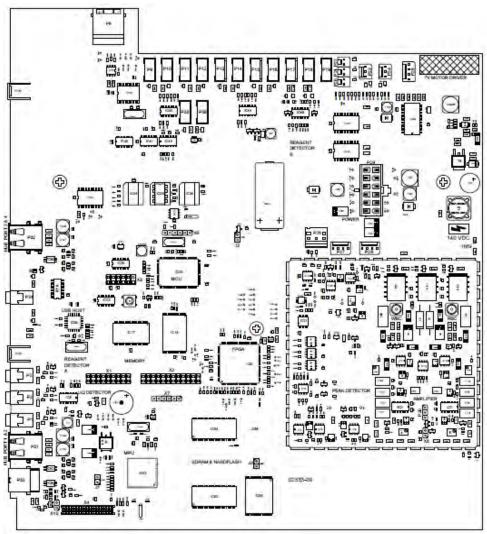
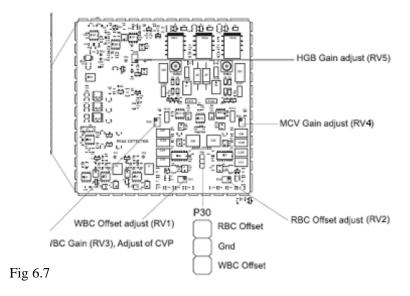


Figure 6.6 New version of USB CPU board and amplifier part in fig 6.7, same adjustment as in older version of board.



Section 6 Version 06

6.3.2 Display PCB

When demounting and mounting a new display PCB, pay attention that all metallic shields and screws are put back in place. Violating this might result in heavy interference on the measured parameters.

6.3.3 Power supply

When mounting a new power supply PCB, be aware that all screws to the chassis are secured and well tightened. Perform the following procedure after changing the PCB and switching on the BM800:

Procedure:

- 1. Connect an mV meter between P30-1 and P30-2 and adjust RV2 for 0.0mV reading.
- 2. Connect an mV meter between P30-3 and P30-2 and adjust RV1 for 0.0mV reading.

6.4 HGB adjust

The HGB adjust function is used to set the light intensity of the HGB diode (=LED) to a level that is correct for the photometer system to work properly. Please note that the HGB adjust function is *not* related to the calibration of the HGB parameter.

Too low of an intensity will flag the HGB parameter with 'HL' and too high of an intensity with 'HH'. If the intensity is far outside of its limits, no HGB value will be displayed.

If HF is displayed check that the diluent level inside WBC measuring chamber between each sample is around 1cm above HGB lamp (=LED).

6.4.1 HGB adjustment for a already installed board

- 1. Check that the BM800 is filled with reagents.
- 2. Go to Service Menu2 and select [HGB]. (Figure 6.8)
- 3. Press the [HGB LED Current] button and set the current to a value where the photometer output reads between 3200-3500.
- 4. Press [SAVE] before leaving this menu. Use password 3819 to be allowed to make the adjustment.

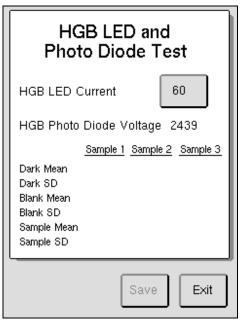


Figure 6.8 See also Section 5.10 and 14.7 for details

The acceptable range for the photometer output is 3200-3800.

Values < 3200 results in an HGB 'HL' message. Values > 3800 results in an HGB 'HH' message.

Note that the LED current and photometer output are not displayed in mA or mV, but only in 'internal' units.

6.4.2 HGB adjustment for new installed board

Note: This process can be used if the HGB adjustment for an already installed board fails.

- 1. Select [HGB] from Service Menu 2.
- 2. Make sure HGB LED current is adjusted to 60 before continuing.
- 3. Locate RV5 on the board, see Figure 6.5. Turn the RV5, clockwise to increase and clockwise to decrease the value of the "HGB Photo Diode Voltage". Adjust the value to 3500 ± 20 .
- 4. Calibrate the HGB accordingly, if the new settings have been changed.

6.5 Mixing cup cleaning/adjust

The internal mixing cup, see Figure 6.9, can be dismantled for cleaning purposes.

Remove the complete mixing cup from its clip-holder and remove the plastic cup, which is fitted with an O-ring and a screw to the lid.

Clean the electrodes see Figure 6.10, with a tissue and distilled water.



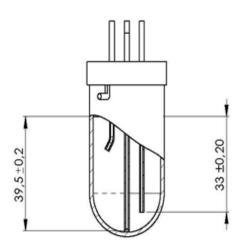


Figure 6.9

Figure 6.10

The electrodes/tubes are fitted to the lid with O-rings. The measurements of the electrodes see Figure 6.9, are critical and should be according to the values shown in Figure 6.10.

The mixing cup electrodes can be tested by selecting the [Beaker Detector] button in Service Menu 2. See Figure 6.11 below.

In home position the display should show '1' (air). Manual filling of the cup with diluent, should switch the indication to '2' (liquid).

Note: Distilled water is detected as 'air'.

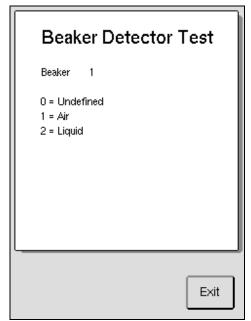


Figure 6.11

6.6 Pipette and measure tube detector

The eight detectors are used to differentiate a filled pipette/measure tube from an empty one. A filled glass unit indicates a '2' (liquid) and an empty glass units indicates a '1' (air). The volume of the glass units are very specific and adjusted carefully by Boule.

6.6.1 Replacement of detectors

See procedure below if a start/stop detector (see Figure 6.12) needs to be replaced:

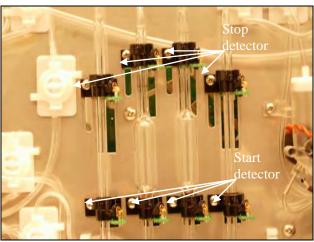


Figure 6.12

- 1. Mark the position of top detector with a pen on the metal plate before the detectors are unscrewed. (This is important to avoiding volume calibration of the glass units).
- 2. Unscrew the screw for the stop and start detectors.
- 3. Detach the cables from the main board.
- 4. Pull the glass unit gently away from the instrument. Release the tube from the lower end of the glass unit.
- 5. Gently release the defective detector and pull it out from the glass unit.
- 6. Start with putting the O-ring over the glass unit before the new detector is placed in the glass unit.
- 7. Put the new detector over the glass tube.
- 8. Make sure to cut off the already pre-formed Tygon tube end before installing the tube over the glass tube end.
- 9. Reinstall detectors in original place.
- 10. Reinstall cables according to Figure 6.4.
- 11. Fix the detectors back into the marked position. (If one of the pipettes was changed press the pipette as far down as possible).

6.6.2 Replacement of glass pipettes

Necessary equipment: one precise syringe with ul scale for measuring tube replacement, and one precise syringe with ml scale for pipettes. Make sure that the correct syringe is available before this process is started. If the glass units need to be replaced perform steps 2-4 in Section 6.6.1.

- 1. Gently release the glass tube from both detectors.
- 2. Mount the o-rings over the glass tube the same as it was before demounting.
- 3. Mount the detectors over the glass unit.
- 4. Reinstall detectors in their original place.
- 5. Reinstall cables according to Figure 6.4.
- 6. Choose [Level detectors] from the Service menu.
- 7. Attach the liquid filled precise syringe to the end of the glass unit.
- 8. Gently press the liquid up until the lower detector activates (2).
- 9. Start to measure the volume from that point and fill the pipettes with 4.5 ml and the measuring tubes with 270ul.
- 10. Adjust the top detector so it indicates that it is filled (2).
- 11. Tighten the detector to the valve wall.
- 12. Empty the glass unit and perform steps 8-10 again to verify that the correct volume is adjusted.

6.7 Replacement of shear valve

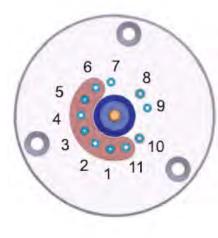
6.7.1 Replacement old model of shear valve 1090927_S

The shear valve must never be opened or repaired by anyone other than Boule Medical AB trained assemblers. Every single shear valve is individual and values from one shear valve are not usable on a different shear valve or the instrument will malfunction. If a shear valve is opened or unassembled by anyone other than a trained Boule Medical AB assembler the three year warranty will be cancelled. A new shear valve must then be purchased from Boule Medical AB.

When the defective shear valve is replaced it should be returned to Boule Medical AB during the warranty period.

Only complete shear valves will be delivered. Separate parts for a shear valve can not be purchased.

- 1. Remove the cables from the display board.
- 2. Unscrew the four screws that hold the display in place.
- 3. Detach the tubes from the shear valve (Make sure that reinstalling of the tubes can easily be done)
- 4. Remove the cables from the shear valve to the main board.
- 5. Unscrew the four screws on the backside of the shear valve and the one screw on the front of the instrument which connects the ground cable to the body of the instrument.
- 6. Unscrew the two screws that hold the shear valve to the valve wall. (Hold on to the shear valve while doing this.)
- 7. Turn the shear valve 90 degree and remove it from the instrument.
- 8. Install the new shear valve into position.
- 9. Screw in the three screws on the backside of the shear valve.
- 10. Screw in the two screws on the valve wall.
- 11. Screw in the last screw on the backside of the shear valve and then fix the ground cable to the instrument body from the shear valve.
- 12. Mount the tubes back on the shear valve according to Figure 6.13. (Make sure that tubes are installed correctly. A misplaced tube will cause a malfunction of the instrument. Check that the tube from the OT-inlet is all the way pressed inside the shear valve tube.)
- 13. Connect the cables according to Figure 6.4.
- 14. Select [Shear valve] from Service Menu 2 and place the new values which are on the sticker attached to the shear valve. (Make sure to add the right value according to the position of the shear valve or else the instrument will malfunction.)
- 15. Choose [SAVE], use password 3819 to accept the new values.
- 16. Calibrate all necessary inlets on the instrument with a Boule Medical AB approved calibrator.
- 17. Choose [Print All Settings] from the Setup Menu and save the new PAS nearby the instrument.



- Aspiration needle/Sample probe inlet tube
- Diluent pipette (V17)
- 3. Aspiration needle/Sample probe outlet Tube (V27)
- 4. Mixing beaker (Bend pipe)
- 5. Human instrument: CAP/Sampler inlet

Vet instrument: Backflush Tube (V16)

- 6. ShearValve Wash (V18)
- 7. Second dilution out (V24)
- 8. RBC chamber
- Longest mixing beaker pipe
- 10. Diluent pipette (V17)
- 11. ShearValve Wash (V18)

Boule

Section 6 Version 06

Replacement new model of shear valve 1091308_S 6.7.2

- 1. Disconnect the cables from the display board.
- 2. Dismount the four screws which hold the display and remove it.
- 3. Disconnect the tubes from the shear valve (Make sure that reconnection of the tubes easily can be done)
- 4. See Figure 2: Remove all of the marked tubes and connectors. (These will be replaced with the tubing kits 50 and 51)
- 5. Disconnect the cables from the shear valve to the main board.
- 6. Dismount the four screws on the backside of the shear valve and the screw on the front of the instrument which connects the ground cable to the instrument chassis.
- 7. Dismount the two screws which hold the shear valve from the right side wall close to the RBC measuring chamber. (Hold on to the shear valve during this step)
- 8. Turn the shear valve 90 degrees and remove it from the instrument.
- 9. Install the new shear valve unit into position.
- 10. Mount the three screws on the backside of the shear valve.
- 11. Fix the shear valve with the two screws from the right side wall.
- 12. Mount the last screw on the backside of the shear valve and then fix the ground cable from the shear valve to the front instrument chassis.
- 13. Connect the tubes from step 3 plus the new tubing kits 50 and 51 on the shear valve according to Figure 1, 3 and 4. (Make sure that the tubes are connected properly. A misplaced tube will cause a malfunction of the instrument. Check that the teflon tube from the OT-inlet and CT-inlet (if present) is pressed all the way inside the shear valve metal tube.
- 14. Connect the cables according to Figure 6.4.
- 15. Select [Shear valve] from Service Menu 2 and store the new values which are printed on the sticker attached at the shear valve. (Make sure to store the correct values according to each position of the shear valve otherwise the instrument will malfunction.)
- 16. Choose [SAVE], use password 3819 to accept the new values.
- 17. Perform two prime sequences in order to fill the shear valve.
- 18. Perform at least two backgrounds or until background values are within limits.
- 19. Calibrate all necessary inlets on the instrument with a Boule Medical AB approved calibrator.
- 20. Choose [Print All Settings] from the Setup Menu and save the new PAS nearby the instrument.

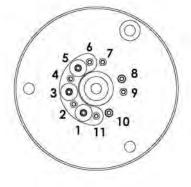
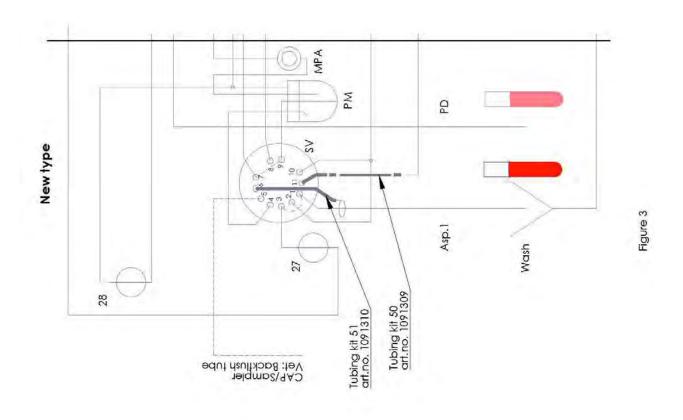
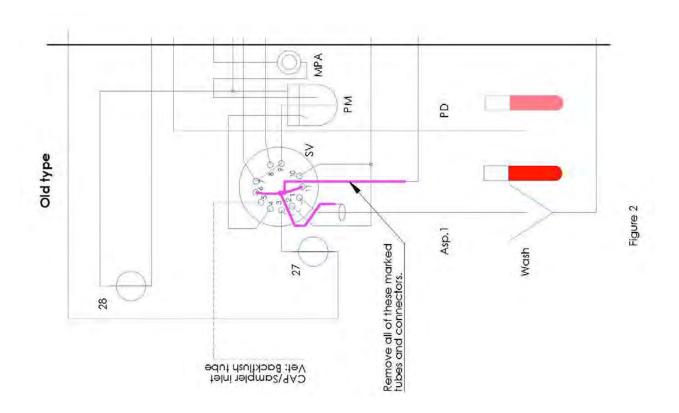
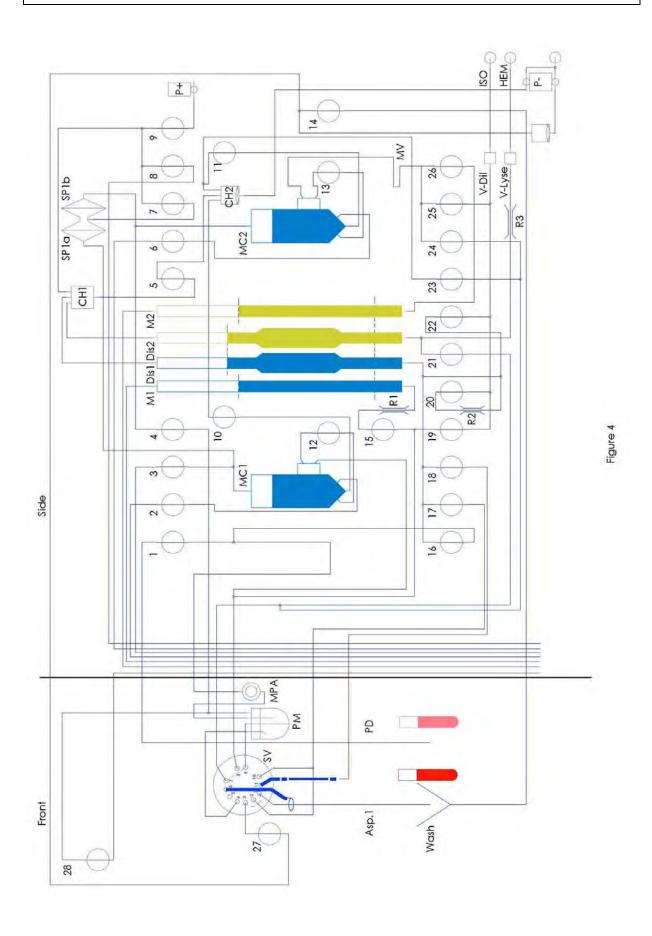


Figure 1

- 1. Aspiration needle/Sample probe inlet tube
- 2. Diluent pipette (V17)
- 3. Aspiration needle/Sample probe outlet inlet tube (V27)
- 4. Mixing beaker (Bend pipe)
- 5. Human instrument: CAP/Sampler inlet
- 6. OT- wash
- 7. Second dilution out (V24)
- 8. RBC chamber
- 9. Longest mixing beaker pipe
- 10. Diluent pipette (V17)
- 11. Shear valve wash (V18)







| Boule | Page 1/12 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 7 Version 05 |

| 7. Inc | dications / error-codes (V05) | 2 |
|--------|-------------------------------|-------|
| | Indications numbering | |
| | Indication Beep Pattern | |
| 1.4 | marcation beep rattern | . 1 4 |

7. Indications / error-codes (V05)

Indications or error-codes are specific instrument situations that in most cases need the attention of the operator and might need service action. This section describes the Indication numbers as well as the recommended action to be taken. The last Indications are logged and can be retrieved by doing a P.I.L. (Print Instrument Log, see Section 8).

In most cases, the BM800 is stopped and the operator has to confirm with [OK] to continue. Indications are grouped to simplify communication between the user and service staff.

The three number indications usually occur after the one or two number indications (1-210). For example, an indication 302 will be displayed due to interference with an OT analysis. It states that the OT cycle was aborted. The first indication (1-210) display is the most important as it describes the issue and how to solve the problem and the three digit indication explains in which cycle the instrument was stopped in. See page 11 in this section for complete 300 cycle list.

For error flags, like DP, DF, LP, LF, TE, SE, TU, TL and DE see chapter 14. Trouble shooting and error guide.

7.1 Indications numbering

Indication series 1 - 19 is reserved for auxiliary errors like battery faults or similar.

Indication series 20 – 29 is reserved for 'Liquid' errors.

Indication series 30 – 39 is reserved for Communication errors between the PCBs (CAN bus).

Indication series 40 - 49 is reserved for Printer and serial output errors.

Indication series 50 - 59 is reserved for General Memory errors.

Indication series 60 – 69 is reserved for EEPROM/HPC (High Performance Controller) errors.

Indication series 70 – 79 is reserved for Shear Valve problems.

Indication series 80 – 89 is reserved for Cap Piercer errors (Closed Tube Adaptor)

Indication series 90 – 99 is reserved for sampling device errors.

Indication series 100-210 is reserved for miscellaneous errors

Indication series 300 -399 is reserved for cycle aborted indication numbers.

| Indications 10 – 29: Auxiliary and Liquid errors | | | | | | |
|--|----|---|--|--|--|--|
| Text shown | # | Explanation | Cause | Action | | |
| E_RTC_BADTM | 10 | Real Time Clock Bad Time | Real time clock not set, or bad backup battery | Set the clock. Change the battery | | |
| E_RTC_HASSTOPPED | 11 | Real Time Clock stopped | Real time clock not set, or bad backup battery | Set the clock. Change the battery | | |
| E-DP_LEVELDET-TIMEOUT | 14 | Level detector timeout for glass pipettes | Could be 0=Undefined liquid detector status | Check level detector status for glass pipettes from service menu | | |
| E_KBD_NOTPRESENT | 18 | Keyboard setting wrong | Set up menu modified wrong | Check Set up menu 2- Regional setup- Keyboard Layout | | |
| E_BBI_NOTSTARTED | 20 | Cycles can not run | Unusual liquid system state, bad system start- up, sub board problems | Check all CAN communication cables and restart instrument | | |
| E_BBI_NOT_RUNNING | 21 | Cycles can not run | Unusual liquid system state, bad system start-up, sub board problems | Check all CAN communication cables and restart instrument | | |
| E_MPAOPENDURINGCYCLE | 22 | MPA adapter removed during cycle | MPA adapter is removed from instrument when a cycle was running | Push back the MPA adapter and run a prime cycle | | |
| E_MPAISOPEN | 23 | MPA adapter removed during cycle | MPA adapter is removed from instrument when a cycle was running | Push back MPA handle | | |
| E_NOWASH_NOREAG | 25 | No wash was performed during standby | Reagent empty | Install new reagent boxes | | |
| E_NOWASH_OTHERREASON | 26 | No wash was performed during standby | Different reason than out of reagent | Run a prime and make sure no other indications appear | | |

| 30-39 Indications: CAN Communication Error | | | | | |
|--|----|---|---|--|--|
| Text shown | # | Explanation | Cause | Action | |
| E_CAN_TX_TIMEOUT | 30 | No CAN bus connection at all | Cable not connected or defect main board | Check CAN cable connections between the boards, replace CPU board | |
| E_CAN_VALVEBOARD_TIMEOUT | 31 | No connection to with valve board | Bad Valve board or cable not connected | Check CAN cable and power connections to valve board, replace valve board | |
| E_CAN_CAPIEBOARD_TIMEOUT | 32 | No connection to with Cap Piercer board | Bad Cap piercer board or cable not connected | Check CAN cable and power connections to Cap board, replace Cap board | |
| E_CAN_SAMPLERBOARD_TIMEOUT | 33 | No connection with the sampler board | Bad Sampler board or cable not connected | Check CAN cable and power connections to sampler board, replace sampler board | |
| E_CAN_DISPLAYBOARD_TIMEOUT | 34 | No connection with the display board | Bad display board or cable not connected | Check CAN cable and power connections to display board, replace display board | |
| E_BIVALVE_STILLTIMEOUT | 35 | Valve communication timeout | Bad valve / cap piercer / sampler board, or cable not connected | Check CAN cable and power connections between all boards | |

| 40 - 49 Indications: Printer Error | | | | | | |
|------------------------------------|----|---------------------------|---|--|--|--|
| Text shown | # | Explanation | Cause | Action | | |
| E_PR_BUSY | 40 | Printer still Printing | Print command given before the previous one has finished | Wait until the printer has finished the print out | | |
| E_PR_NOTREADY | 41 | Printer is not ready | Printer off-line, out of paper or not connected | Power off instrument and printer. Power on instrument and then printer after menu light up | | |
| E_PR_TIMEOUT | 42 | Printer timeout | Printer off-line, out of paper or not connected | See above | | |
| E_PR_BADSETUP | 43 | Bad printer setup | The selected printer is not matching the print format setup | Check Ticket format and Print setup | | |
| E_SN_BUSY | 44 | Serial port still sending | Send command given before the previous one has finished | Wait until the data transfer is finished | | |
| E_SN_TIMEOUT | 45 | Serial port timeout | The serial port is not connected, bad serial cable or bad setup on the instrument | Check the serial setup settings and cable connection | | |
| E_SN_PROTOERROR | 46 | Serial protocol Error | Bad serial connection, missing external serial receiving program, or problem with external serial receive program | Check cable connection and power off/on Instrument and LIS computer if problem persist | | |

| Boule | Page 5/12 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 7 Version 05 |

| E_USB_TIMEOUT | 48 | USB communication timeout | No connection between the instrument and the USB subsystem | Restart Instrument. If indication persist. Perform "USB firmware rescue procedure, Replace CPU board |
|---------------|----|---------------------------------|--|--|
| E_USB_ERROR | 49 | USB communication error | Bad connection between the instrument and the USB subsystem | See above |

| 50 - 59 Indications: Bad me | 50 - 59 Indications: Bad memory error | | | | | | | | |
|-----------------------------|---------------------------------------|--|---|---|--|--|--|--|--|
| Text shown | # | Explanation | Cause | Action | | | | | |
| E_NV_LOST_BOTH | 50 | Bad configuration memory content in both battery backed RAM and EEPROM | Software upgrade, or hardware problem | Press OK to initialize the configuration memory content, check that shear valve setting and calibration factors seems correct. This can appear after software upgrade | | | | | |
| E_NV_LOST_RAM | 51 | Bad configuration memory content in battery backed RAM only | CPU PCB replacement. Battery problem, or hardware problem | Press OK to copy configuration memory content from EEPROM to battery This can appear after software upgrade | | | | | |
| E_NV_LOST_EE | 52 | Bad configuration memory content in EEPROM only | Missing or uninitialized EEPROM chip, hardware problems | Press OK to copy configuration memory content from battery backed RAM to EEPROM This can appear after software upgrade | | | | | |
| E_NV_RAM_EE_DIFFERS | 53 | Configuration memory content in battery backed RAM and EEPROM are both correct but different | The EEPROM chip has been moved from another main board, this happens after main board replacement, press "EE" and not RAM | Press "EE" to copy configuration memory content from EEPROM, press "RAM" to copy configuration memory content from battery backed RAM to EEPROM if you want to use that configuration | | | | | |
| E_ILO_LOST | 54 | Instrument log lost | Software upgrade, Battery problem, hardware problem | Press "OK" to initialize the instrument log. This can appear after software upgrade | | | | | |
| E_SMEM_LOST | 55 | Sample Memory is lost | Software upgrade, battery problem, hardware problem | Press "OK" to initialize an empty sample memory, This can appear after software upgrade | | | | | |
| E_XB_LOST | 56 | The Xb memory is lost | Software upgrade, battery problem, hardware problem | Press "OK" to initialize an empty Xb memory. This can appear after software upgrade | | | | | |

| Boule | Page 6/12 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 7 Version 05 |

| Text shown | # | Explanation | Cause | Action |
|-----------------|----|----------------------------------|--|--|
| E_I2C_EE | 60 | EEPROM chip problem | Bad or missing EEPROM chip | Replace EEPROM,IC35 and copy configuration memory content to the new chip |
| E_EE_WR_TIMEOUT | 61 | EEPROM chip write problem | Bad EEPROM chip | Replace EEPROM, IC35 and copy configuration memory content to the new chip |
| E_EE_MISMATCH | 62 | EEPROM chip write verify problem | Bad EEPROM chip | Replace EEPROM, IC35 and copy configuration memory content to the new chip |
| E_HPC_TIMEOUT | 63 | HPC hardware problem | Bad or missing HPC, or mainboard problem | Replace HPC, IC34 or replace main board if bad |
| E_HPC_ERROR | 64 | HPC hardware problem | Bad HPC, or main board problem | Replace HPC,IC34 or replace main board if bad |
| E_HPC_VERSION | 65 | Wrong HPC version | Wrong HPC version | Replace HPC, IC34 |
| E_HPC_CONTENT | 66 | Wrong HPC content | Wrong HPC content | Replace HPC, IC34 |

| 70 - 79 Indication: Shear Valve problems | | | | | | |
|--|----|--|---|---|--|--|
| Text shown | # | Explanation | Cause | Action | | |
| E_SHVMOTOR_MOVING | 70 | Internal problem | Internal problem | Restart instrument, check shear valve cables, check 24V on CPU board, replace CPU board | | |
| E_SHVMOTOR_TIMEDOUT | 71 | The share Valve are not able to change the positions | The share Valve is stuck or the motor is not working | Manually press diluent through pipe 11 and 6 several time and in same time Init button from Service menu 2-Shear valve | | |
| E_SHVMOTOR_START_BAD_POS | 72 | Internal problem | Internal problem | Restart instrument, check shear valve cables, check 24V on CPU board, replace CPU board | | |
| E_SHVMOTOR_START_BAD_ADVAL | 73 | Bad position indicator reading | The position indicator is not working proper or wrong adjustments setup | See indication 71, check that shear valve settings is correct | | |
| E_SHVMOTOR_INIT_BAD_ADVAL | 74 | Bad position indicator reading during initialization | The position indicator is not working proper or wrong adjustments setup | Check motor and position indicator connections. | | |
| E_SHVMOTOR_INIT_NOT_DONE | 75 | The shear valve initialization was not done successfully | Bad position indicator, The share Valve is stuck or the motor is not working | See Indication 71 and check shear valve positions | | |

| 80-89 Indication: Needle movement error for Cap and Sampler | | | | | | | |
|---|----|---|---|--|--|--|--|
| Text shown | # | Explanation | Cause | Action | | | |
| E_NDLMOTOR_START_FAILED | 80 | The needle motor didn't start | Needle motor problem, bad needle position indicators, bad cap piercer / sampler board | Check that needle mechanic is not blocked and that needle can move up and down | | | |
| E_NDLMOTOR_RUN_FAILED | 81 | Bad needle position indicators | Needle movement obstructed, Needle motor problem, Bad needle position indicators, bad cap piercer / sampler board | Check needle motor connections. Check possible liquid leakage to cap/sampler board sensors, see above | | | |
| E_NDLMOTOR_GUARD | 82 | Needle guard emergency stop | Cap piercer board: lid opened during upward needle movement, sampler board: needle guard didn't move correctly | Keep lid closed, check Lid switch Check needle guard movement for sampler | | | |
| E_NDLMOTOR_TIMEOUT | 83 | Needle movement problem | Needle motor problem, needle position indicator problem. | Clean/grease needle mechanic. Check needle up and down movement from service menu. Check board sensors Check link arm and Allen screw for sampler mechanic | | | |
| E_NDLMOTOR_MOVING | 84 | Internal Error | Internal Error | Restart instrument, if problem persists, contact service. | | | |
| E_NDLMOTOR_STILLTIMEOUT | 85 | Needle motor communcation problem | Bad cap piercer / sampler board, or cable not connected | Check CAN and power cables to Cap/sampler board, restart instrument | | | |

| 90-99 Indicator: Sampler (Only if you have Sampling device installed) | | | | |
|---|----|---|--|--|
| Text shown | # | Explanation | Cause | Action |
| E_WHLMOTOR_START_FAILED | 90 | The primary wheel motor didn't start | Primary wheel motor problem, bad primary wheel position indicators, sampler needle problem, primary wheel guard indicators, bad sampler board | Check wheel movement, switch between wheel 1 and 2. Check sensors from Service menu- Needle |
| E_WHLMOTOR_RUN_FAILED | 91 | Bad primary wheel position indicators | Primary wheel movement obstructed, Primary wheel motor problem, bad primary wheel position indicators, bad sampler board | See above. Check that motor/gear box is not bad. Check for loose mechanic. Switch place with mixer motor/gear box |
| E_WHLMOTOR_TIMEOUT | 92 | Bad primary wheel position indicators | Primary wheel movement obstructed, Primary wheel motor problem, bad primary wheel position indicators, bad sampler board | See above |
| E_WHLMOTOR_GUARD | 93 | Bad primary wheel guard indicators | Sampler needle problem, bad primary wheel guard indicators, bad sampler board | See action in Indication 90 and check that needle guard can move up and fix the sample cone on the wheel |
| E_WHLMOTOR_STILLTIMEOUT | 94 | Primary wheel motor communication problem | Bad sampler board, or cable not connected | Check CAN and power cables to sampler board |

| Boule | Page10/12 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 7 Version 05 |

| 100- Indicator: Miscellaneous, Indications 100 to 210 are very rear, see below indications that we have experience from this interval | | | | |
|--|-----|--|--|---|
| Text shown | # | Explanation | Cause | Action |
| E_CAN VALVEBOARD_RESTART | 159 | Processor on Valve board restart of some reason | Bad power connection from power board to valve board | Check power cable and all pin connectors to valve board, remove cable and clean connectors, Replace, cable, valve board |
| Text shown | # | Explanation | Cause | Action |
| E_CAN CAPIEBOARD_RESTART | 160 | Processor on Cap board restart of some reason | Bad power connection from power board to cap board | Check power cable and all pin connectors to cap board, remove cable and clean connectors, Replace, cable, cap board |
| Text shown | # | Explanation | Cause | Action |
| E_CAN SAMPLERBOARD_RESTART | 161 | Processor on Sampler board restart of some reason | Bad power connection from power board to sampler board | Check power cable and all pin connectors to sampler board, remove cable and clean connectors, Replace, cable, sampler board |
| Text shown | # | Explanation | Cause | Action |
| E_CAN DISPLAYBOARD_RESTART | 162 | Processor on Display board restart of some reason | Bad power connection from power board to display board | Check power cable and all pin connectors to display board, remove cable and clean connectors, Replace, cable, display |

Other possible indications are very rear. Please contact service@boule.se in case some unique indications appear which is not present in the list.

300 Cycle list, describes in which mode the instrument stopped.

| N: | Description | N: | Description |
|-----|------------------------------------|-----|---|
| 301 | Init Cycle | 321 | OT Clot Removal Cycle |
| 302 | Ot Count Cycle | 322 | Bad MPA/MCI Open Prime Cycle |
| 303 | Predilute Count Cycle | 323 | Standby Enter Cycle |
| 304 | MPA/MCI Count Cycle | 324 | Standby Exit Cycle |
| 305 | CPD Count Cycle | 325 | Power Down Cycle |
| 306 | Autosampler Count Cycle | 326 | Power Up Cycle |
| 307 | Failed OT Pipette Wash Cycle | 327 | Power On Close All Valves Cycle |
| 308 | Power Up Autocount Cycle | 328 | Power On Open All Valves Cycle |
| 309 | Standby Exit Autocount Cycle | 329 | Fault Standby Openall Valves Cycle |
| 310 | OT Clot Prevention Autocount Cycle | 330 | Fault Standby Closeall Valves Cycle |
| 311 | Standby Wash Autocount Cycle | 331 | Reagent Levels Check Cycle |
| 312 | Pre Standby Wash Cycle | 332 | Pre-check Fill Cycle |
| 313 | Post Standby Wash Cycle | 333 | Pre-check Empty Cycle |
| 314 | Prime Cycle | 334 | Pre Dispense Cycle |
| 315 | Fill Cycle | 335 | Dispense Cycle |
| 316 | Empty Cycle | 336 | Post Dispense Cycle |
| 317 | Orifice Clean Cycle | 337 | Shear Valve Init Cycle |
| 318 | Cleaning Fill Cycle | 338 | OT Back Flush Cycle |
| 319 | Cleaning Empty Cycle | 339 | Power On Maintain Standby Diluent Levels Cycle |
| 320 | OT Clot Prevention Cycle | 340 | Standby Fault Maintain Standby Diluent Levels Cycle |

7.2 Indication Beep Pattern

BM800 main board application has some beep patters, that indicates different issues or happenings.

| S | short beep (0,1 s or 0,05 s) |
|---|------------------------------|
| L | long beep (0,4 s or 0,25 s) |
| P | pause during repeat (0,6 s) |
| M | medium beep (0,15 s) |

^{*} Only present in mb app V2.5 / mb bm V3.0 .

^{***} Only present in mb app V2.5.1

| Pattern | Repeats? | When | Why |
|-----------|--------------|--------------------------|--------------------------------|
| S-S-L-P | Continuously | Any time | Display board failure, but it |
| | | | worked at power on |
| S-L-S-P | Continuously | After power on | Display board failure |
| S-L-L-P | Continuously | After power on | CAN bus failure |
| L-S-S-P | Continuously | After power on | RAM failure |
| L-S-L-P* | Continuously | After power on | Main board boot monitor |
| | | | failure |
| L-L-S-P* | 3 times | After power on | Main board application failure |
| L-L-S-P** | Continuously | After power on | "Trampoline boot" failure. |
| L-L-S-P* | Continuously | During USB upgrade of | Main board application |
| | | main board application | upgrade failure |
| S-S-S* | Once | After a main board | Main board application USB |
| | | application failure | recovery upgrade started |
| S-S-S*** | Once | After a display board | Display board application |
| | | application failure | recovery upgrade started |
| S-S-S | Once | Any time | Going to standby in 2 minutes |
| M-M | Once | During count cycle | At least one parameter has a |
| | | | serious flag. |
| M-M | Once | End of cycle | Reagent empty. |
| L | Once | Any time | Indication / error |
| M | Once | Any time | Warning |
| S | Once | Beginning of count cycle | Aspiration succeeded |
| L | Once | Beginning of count cycle | Aspiration failed |
| S-S-S-S | Once | After aspiration | Wash device open warning |
| L-L | Once | Middle of count cycle | OT wash failure |
| L-P | Continuously | Any time | MPA open when it should be |
| | | | closed. |

^{**} Only present in USB-enabled 800:s with mb app V2.5.1 (or later) together with mb bm V2.x.

| Boule | Page | 1/8 |
|-----------------------------------|-------------------|------|
| Service manual BM800 Doc No 01959 | Section 8 Version | ı 03 |

| 8. Ge | neral (V03) | 2 |
|-------|-------------------------------|---|
| | Print All Settings (P.A.S.) | |
| 8.2 | Print Instrument Log (P.I.L.) | 5 |

8. General (V03)

This section describes the printout of instrument specific settings, statistics and logging. Both printouts must be saved in the end-user file of the distributor for maintenance/service issues.

8.1 Print All Settings (P.A.S.)

Instrument settings are defined as being user or manufacturer settings that are specific for the distributor and/or end-user. A printer must be connected and [Print All Settings] (P.A.S.) selected from the Setup menu.

Please note that the printed list might differ between different software versions and can be altered by Boule without notice. A typical printout is shown below. Most of the printed text/settings are obvious and do not need further detailed information.

A "Print All Settings" should be performed after the installation of the instrument at the end-user. A copy must be saved in the service/maintenance file at the distributor to retrieve the original settings in case of operator/maintenance mistakes/faults.

```
Print all settings
Printed: 21/04/2006 15:00:21
Serial no: 10107
Firmware: 2.1.0b12
Options: MH,QC,MPA,MIX,CD
Conf. init: 20/04/2006
CALIBRATION FACTORS
    OT MC PD
RBC +4,0 +4.0 +4.0
MCV +0.6 +0.6 +0.6
HGB +10.0 +10.0 +10.0
WBC +10.0 +10.0 +10.0
RDW% 6500 6500 6500
RDWa 6800 6800 6800
PDW 7300 7300 7300
ANALYSIS PROFILES
Default analysis profile: 1
Analysis profile 1
Name: BLOOD
PLT/RBC float. discr.:
                      15:30
PLT/RBC fix. fallb. discr.: 27
PLT hist. max. scale:
PLT hist. filter,format:
                      7,1
RBC hist. max scale:
                      250
RBC hist. filter, format:
                      2,1
WBC hist. max scale:
                       450
WBC hist. filter, format:
                      4,1
WBC hist. alw. lines:
                      []
WBC discr. mode:
WBC fixed discr. pos.:
                       45
WBC diff. method:
                       1
                                               Swelab Alfa 2
WBC fixed diff MID:
                      140:180
                                               Swelab Alfa
                      40:360
WBC float diff range:
Incl. in "Xb", "stat all":
                     [X],[X]
Background mode:
                       []
```

```
Normal ranges:
RBC 3.50 5.50 WBC 3.5 10.0
MCV 75.0 100.0 LYM% 15.0 50.0
HCT 35.0 55.0 MID% 2.0 15.0
PLT 100 400 GRA% 35.0 80.0
MPV 8.0 11.0 LYM 0.5 5.0
HGB 11.5 16.5 MID 0.1 1.5
MCH 25.0 35.0 GRAN 1.2 8.0
MCHC 31.0 38.0 RDW% 11.0 16.0
RDWa 30.0 150.0 PCT 0.01 9.99
PDW 0.1 99.9 LPCR 0.1 99.9
Analysis profile 2
Name: BACKGROUND
PLT/RBC float. discr.: 15:30
PLT/RBC fix. fallb. discr.: 27
PLT hist. max. scale:
PLT hist. filter, format:
                    7,1
RBC hist. max scale:
                     250
RBC hist. filter,format: 2,1
WBC hist. max scale:
                      450
WBC hist. filter,format: 4,1
WBC hist. alw. lines: []
WBC discr. mode:
                     0
WBC fixed discr. pos.:
                     0
WBC diff. method:
                     1
              Swelab Alfa 2
WBC fixed diff MID:
                          140:180
                          Swelab Alfa
WBC float diff range:
                     40:360
Incl. in "Xb", "stat all": [],[]
Background mode:
                     [X]
Normal ranges:
RBC 0.00 0.02 WBC 0.0 0.2
MCV 0.0 0.0 LYM% 0.0 0.0
HCT 0.0 0.0 MID% 0.0 0.0
PLT 0 20 GRA% 0.0 0.0
MPV 0.0 0.0 LYM 0.0 0.0
HGB 0.0 0.2 MID 0.0 0.0
MCH 0.0 0.0 GRAN 0.0 0.0
MCHC 0.0 0.0 RDW% 0.0 0.0
RDWa 0.0 0.0 PCT 0.00 0.00
PDW 0.0 0.0 LPCR 0.0 0.0
XB
MCV 86.8 92.2
MCH 29.6 31.4
MCHC 33.0 35.0
LOCALE
Language:
Param. units grp A,B,C,D: 1,1,1,1
Parameter name system:
Keyboard layout:
EXTERNAL
Printer type:
                  1
Paper type:
                  1
Print ticket format:
Show flag texts on ticket: []
One ticket per page:
                    []
Auto print mode:
                    2
Manual print mode:
                     2
Auto send mode:
                    0
Manual Send mode:
                      2
Send with ACK:
                    [X]
```

| Boule | Page 4/8 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 8 Version 03 |

Barcode reader type: STANDBYDisplay saver time (min): 15 Standby time (min): 120 Standby exit auto bgcnt: [X] INSTRUMENT SETTINGS Blood detector, normal: 0.0 Mixer present: [X] PLT offset: 0
High altitute comp.: 0 Block predil start: [X] Store raw data: [] HGB LED setting: Shear valve: 1: 750 21: 365 23: 380 3: 2600 Shear Valve Position End of report

Figure 8.1

8.2 Print Instrument Log (P.I.L.)

The Instrument Log contains the most recent instrument use, actions, errors and important statistics.

A "Print Instrument Log" should be performed after the installation of the instrument at the end-user. A copy must be saved in the service/maintenance file at the distributor to check the daily use of the BM800 and in case of instrument, operator or maintenance mistakes/faults, proper service actions are greatly simplified. Please note that the printed list might differ between software versions and can be altered by Boule without notice.

Instrument log

Printed: 21/04/2006 15:01:14

Serial no: 10107 Firmware: 2.1.0b12

Options: MH,QC,MPA,MIX,CD

Log init: ../../.... Conf. init: 20/04/2006

Subboard firmware Versions:

Main board: Boot: V 2.1 HPC: V 7 Ser#: (not set) Display board:

Appl: CAN 1 V 2.1 Disp 2

Boot: CAN 1 V 2.1 Ser#: 65535 Valve board: Appl: CAN 1 V 2.1

Boot: CAN 1 V 2.1 Ser#: 65535

Power on and last cycles:

on: 20/04/2006 12:25:44

lc: 20/04/2006 12:25:58 27 POCAV ok

on: 20/04/2006 12:27:41

lc: 20/04/2006 12:27:41 27 POCAV ok on: 20/04/2006 13:16:01

lc: 20/04/2006 13:16:02 27 POCAV 71

on: 21/04/2006 08:17:53

lc: 21/04/2006 08:17:54 27 POCAV ok

on: 21/04/2006 09:45:45

lc: 21/04/2006 12:49:51 14 PRIME 314

on: 21/04/2006 12:56:26 lc: 21/04/2006 13:05:18 17 BURN ok

on: 21/04/2006 13:27:07

lc: 21/04/2006 14:45:38 3 PDCNT ok

on: 21/04/2006 14:58:35

lc: 21/04/2006 14:58:35 27 POCAV ok

Manual cycles:

21/04/2006 13:52:34 2 OTCNT ok 21/04/2006 13:53:49 14 PRIME ok 21/04/2006 13:57:05 2 OTCNT ok 21/04/2006 13:58:19 2 OTCNT ok 21/04/2006 14:01:14 2 OTCNT ok

21/04/2006 14:17:33 16 EMPTY ok

21/04/2006 14:21:42 15 FILL ok

```
21/04/2006 14:26:39 14 PRIME ok
21/04/2006 14:29:33 2 OTCNT ok
21/04/2006 14:30:47 2 OTCNT ok
21/04/2006 14:32:24 2 OTCNT ok
21/04/2006 14:34:15 2 OTCNT ok
21/04/2006 14:37:04 2 OTCNT ok
21/04/2006 14:38:22 2 OTCNT ok
21/04/2006 14:42:47 3 PDCNT ok
21/04/2006 14:45:38 3 PDCNT ok
Automatic cycles:
20/04/2006 10:36:03 27 POCAV ok
20/04/2006 12:25:58 27 POCAV ok
20/04/2006 12:27:41 27 POCAV ok
20/04/2006 13:16:02 27 POCAV 71
21/04/2006 08:17:54 27 POCAV ok
21/04/2006 09:45:45 27 POCAV ok
21/04/2006 12:56:26 27 POCAV ok
21/04/2006 13:27:07 27 POCAV ok
21/04/2006 14:58:35 27 POCAV ok
Indications:
50 20/04/2006 12:25:44
55 20/04/2006 12:25:56
71 20/04/2006 12:47:24 37 SHVIN
71 20/04/2006 12:48:00 37 SHVIN
71 20/04/2006 12:48:36 37 SHVIN
71 20/04/2006 12:48:57 37 SHVIN
71 20/04/2006 12:49:12 37 SHVIN
71 20/04/2006 12:51:42 37 SHVIN
71 20/04/2006 12:52:32 37 SHVIN
71 20/04/2006 13:16:04 1 INIT
71 20/04/2006 13:16:39 37 SHVIN
Tech info about last 3 samples:
 SEQ
         DATE
                  TIME AM
DPD1 DPU1 DPD2 DPU2 LPD LPU
 ASP
         RTD RTU WTD WTU
XFER
          RMIN RMAX WMIN WMAX
HGBD Cv*10 HGBB Cv*10 HGBS CV*10
Cycle counters
Blood=1 Blank=13 Wash=0 Prime=5
Orif. cl. M=1 AR=0 AW=0
Shear valve motor run info:
12: 47 23: 42 13: 86
21: 40 32: 47 31: 86
End of report
```

Figure 8.2

Instrument serial numbers/software

The first section of P.I.L. contains instrument hard/software settings like the serial number of the chassis/PCBs and software versions of the application and sub-units.

Last use of instrument

The most recent actions of the instrument are saved in 'Power on and last cycles' In the example above:

On: 14/10/2005 15:56:11 The instrument was switched on at the stated date/time Lc: 14/10/2005 15:58:12 2 OTCNT ok Last Cycle performed at stated date/time. After this cycle

the BM800 was switched off.

The next text in this row is read as follows:

2 = Cycle number (printed for error tracing at Boule only) OTCNT = Open Tube Count (sample is run from the open tube inlet)

Ok = No instrument errors/indications

Short abbreviations are used at the Last Cycle row, see some examples below:

| Code | Description | Code | Description |
|-------|---------------------------------------|-------|---|
| INIT | Init Cycle | CLREM | OT Clot Removal Cycle |
| OTCNT | Ot Count Cycle | ВМРАО | Bad MPA/MCI Open Prime Cycle |
| PDCNT | Predilute Count Cycle | STENT | Standby Enter Cycle |
| MCCNT | MPA/MCI Count Cycle | STEX | Standby Exit Cycle |
| CPCNT | CPD Count Cycle | PDOWN | Power Down Cycle |
| ASCNT | Autosampler Count Cycle | PU-AC | Power Up Cycle |
| OTWFW | Failed OT Pipette Wash Cycle | POCAV | Power On Close All Valves Cycle |
| PU-AC | Power Up Autocount Cycle | POOAV | Power On Open All Valves Cycle |
| SX-AC | Standby Exit Autocount Cycle | SFOAV | Fault Standby Openall Valves Cycle |
| CL-AC | OT Clot Prevention Autocount Cycle | SFCAV | Fault Standby Closeall Valves Cycle |
| WASHC | Standby Wash Autocount Cycle | RGCHK | Reagent Levels Check Cycle |
| WASHP | Pre Standby Wash Cycle | PR-FI | Pre-check Fill Cycle |
| WASHO | Post Standby Wash Cycle | PR-EM | Pre-check Empty Cycle |
| PRIME | Prime Cycle | PR-DS | Pre Dispense Cycle |
| FILL | Fill Cycle | DISP | Dispense Cycle |
| EMPTY | Empty Cycle | PO-DS | Post Dispense Cycle |
| BURN | Orifice Clean Cycle | SHVIN | Shear Valve Init Cycle |
| CFILL | Cleaning Fill Cycle | OTBKF | OT Back Flush Cycle |
| CEMPT | Cleaning Empty Cycle | POMDL | Power On Maintain Standby Diluent Levels Cycle |
| CLPRV | OT Clot Prevention Cycle | SFMDL | Standby Fault Maintain Standby Diluent Levels Cycle |

Manual Cycles

Manual cycles are cycles initiated by the user. The printout is obvious.

| Boule | Page 8/8 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 8 Version 03 |

Automatic Cycles

Automatic cycles are actions taken by the BM800 itself without operator interaction. It might contain automatic wash cycles (WASHP), enter standby mode (STENT), etc.

Indications

Indications are defined as being instrument or environment (mains power) abnormalities. The first 2-3 digits give the 'error-code' followed by the date and time. Detailed information of 'Indications' (error-codes) are provided in this manual in Section 7.

Technical information about last 3 samples

| SEQ: | Sequence number | DATE: Date |
|-------|--------------------------------|--|
| TIME: | Time | AM: Analyze Mode |
| DPD1: | Diluent Pipette Down firs time | DPU1: Diluent Pipette Up first time |
| DPD2: | Diluent Pipette Down firs time | DPU1: Diluent Pipette Up second time |
| LPD: | Lyse Pipette Down | LPU: Lyse Pipette Up |
| ASP: | Aspiration time | PMPW: Mean time for PLT(10fl) to pass orifice |
| RTD: | RBC measuring Tube Down | RTU: RBC measuring Tube Up |
| WTD: | WBC measuring Tube Down | WTU: WBC measuring Tube Up |
| XFER: | Transfer time PM cup | HBF: Time to fill diluent up to LED after sample |
| RMIN: | RBC Min cell flow/sec | RMAX: RBC Max cell flow/sec |
| HGBD: | HGB Dark | HGBB: Blank |
| HGBS: | HGB Sample | |

Cycle Counter

Blood: Inlet blood analysis Blank: Background Analysis

Wash: Wash cycles Prime: Prime cycles

Or if: Orifice clean | M: Manual | AR: Automatic RBC | AW: Automatic WBC

Shear Valve motor run info:

Shear Valve position information about mechanical loose in motor/gear box

| 2 |
|----|
| 2 |
| 3 |
| 4 |
| 5 |
| 6 |
| 6 |
| 8 |
| 9 |
| 10 |
| 13 |
| 14 |
| 16 |
| 16 |
| 16 |
| 17 |
| 17 |
| 18 |
| 18 |
| |

9. Interface / Communication (V06)

This section describes the data format transferring as well as other 'data' issues like software upgrading and printer selection. The reader must have basic understanding of serial data communication, printer- and XML protocol in case of host programming. If using hosts programming contact Boule Medical for latest XML-protocol or download this from our support web pages. In older version of instrument with serial number below 13000, we only have possibility to transfer the patient results through RS232 serial port. This older generation also has a parallel port for printer connection. In later version of BM800 with serial number above 13000 we also have an USB option. In these instruments we can transfer data through USB port, connect printer and barcode reader.

It is also possible to use USB-RS232 serial converter cable or USB-Parallel printer converter cable if this would be requested as interface.

As instrument send the result in xml format, LIS program must be modified to import patient result. This modification is normally an IT procedure and not a quick fix from distributor or instrument supplier. As many different LIS program and request are available on the market, Boule can not offer a standard solution for this purpose. We can explain how to set up the interface connection and forward the communication protocol, rest of the work must be done from IT department in clinic or hospital.

Today we can offer a middleware which can be installed in the LIS computer. This Boule data interface program will convert the xml result file to a text file or an excel folder. In this case it will be easier for LIS program to import the patient result file. Boule data interface program together with installation instructions will be available to download through our support web page.

As we do not use any standard operating system in BM800, end user/distributors can not download any printer drivers in to instrument. This means that we have some limitations regarding printer models in BM800. Today the USB printer must support printer language **PCL5e/c**. This information can usually be found from each printer support web page under specifications and printer language. In case **Host based** will be mention from specifications, then the printer will not work in BM800. Recommendation about some working printer models in BM800 can be forward from Boule on request.

Also printers which support IBM pro printer/Epson compatible (matrix) together with thermo printer Seiko DPU414 will work together with BM800

9.1 Interface with USB CPU board

From serial number 13000 (human) and in all Veterinary instruments we have the option to interface LIS, printer, barcode and keyboard through USB ports.

From serial number 13000 to 17751 (human), < 51501(Vet 17p) and < 52251(Vet 19p) we also have the option to use RS232 serial connection for LIS interface.

From serial number 17752 (human), 51502(Vet 17p) and 52252(Vet 19p), all this instruments will only have USB port as interface connection. This means that barcode reader, LIS, printer and keyboard must be interfaced through USB. It is possible to use USB-RS232 and USB-Parallel converter if this is requested. It is also possible to send the xml patient result to an USB pen drive.

After hardware configuration, Serial set up menu must be configured, see user manual chapter 4.

9.1.1 LIS interface



CPU board with only USB ports (1091373_S CPU board Human) (1091394_S CPU board Vet)



CPU board with USB, RS232 and Parallel (Not available as spare part anymore) (USB CPU board to the left replace)

For connection to LIS from USB port, a standard USB A to USB B cable should be used. This cable should be connected to USB device port in lower part of CPU board. Correct USB driver's needs to be installed to LIS computer. Drivers and installation instruction can be downloaded from distributor support web page depending on which operating system LIS computer uses. In case RS232 serial connection is preferred, an USB-RS232 converter can be used together with a crossed version of serial cable.



USB A-USB B cable

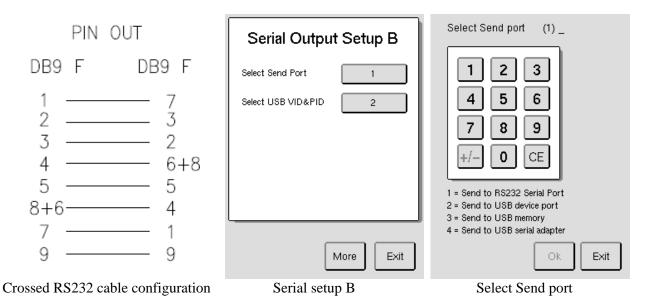


USB-RS232 converter



RS232 serial cable

Note. In case USB-RS232 converter is used then SW2.7.5 or higher must be installed. RS232 cable which will be connected to RS232 converter must be a standard **crossed** pin configured. Depending on which USB communication that is used, Serial set up menu must be correct configured, see screen shots below.



9.1.2 Printer interface

Printer cables that can be used would be as below depending on which CPU board model that is present inside instrument. Print setup menu must be configured correct as well.

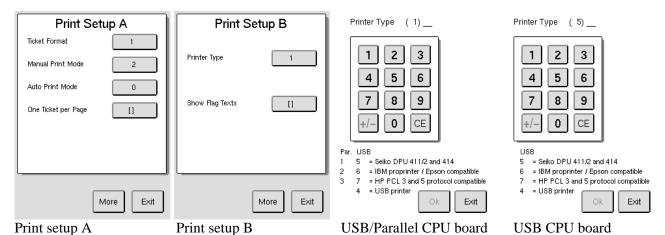
Note. To use USB-Parallel converter, SW 2.7.5 or above must be installed.



As mention in section 9.Interface/communication, we do not use any standard operating system in BM800 and we can not download any printer drivers from outside. This means that we have some limitations regarding printer models.

Today the printer must support printer language PCL5e/c. This information can usually be found from each printer support web page under specifications and printer language. In case **Host based** will be mention from specifications, the printer will **not** work in BM800

Also printers which support IBM pro printer/Epson compatible (matrix) together with thermo printer Seiko DPU414 can work together with BM800.During installation make sure that Print setup is correct configured. See screen shots below

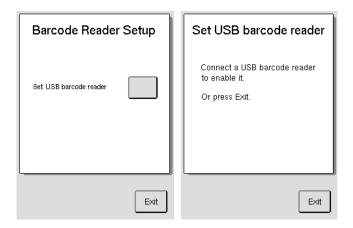


9.1.3 Barcode interface

Today we use USB barcode readers in all new instruments. In the past we used an RS232 serial barcode reader in older instruments. This RS232 barcode reader is still available as spare part to support non USB boards. In case a CPU board with USB and RS232 serial port needs to be replaced we can offer a USB board today. To be able to use RS232 barcode reader with new board, barcode cable can be replaced. Also SW 2.7.5 or above must be installed.



After replacement go to Barcode setup and follow instruction from display.



9.2 Interface with non USB CPU board

First generation of BM800 with serial number 10000 to 12999 does not have any USB port available on CPU board. This board has RS232 and parallel ports available. This means that LIS must be connected through RS232 serial cable, printer through parallel printer cable and barcode reader through serial connector.







CPU board with no USB ports

Serial cable (straight connected) Parallel printer cable

9.2.1 RS232 Serial cable configuration

In instruments with RS232 port present on CPU board we need to use a straight cable configuration to communicate with LIS computer.

This cable can be purchased in local computer stores or produced as below drawings.

The connections from the BM800 to an external PC must be according to the drawing below:

PC Computer using a 9 pin RS232

1 D3 (000

| Cable end BM800 | Cable end PC |
|-------------------|-------------------|
| 9 Pin Female DSUB | 9 Pin Female DSUB |
| | |
| 2 | 2 |
| 3 | 3 |
| 5 | 5 |
| 7 | 7 |
| 8 | 8 |
| | |

| Boule | Page 7/18 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 9 Version 06 |

The pin configuration for the 9 Pin BM800 female connector is as follows:

1. N. C. $\overline{T}\overline{X}\text{-}OUTPUT$ 2. $\overline{R}\,\overline{X}$ -INPUT 3. N.C. 4. **GND** 5. 6. N.C. 7. CTS-INPUT **RTS-OUTPUT** 8.

N.C.

The input and output follows strictly the RS232 specifications. Serial parameters are set to fixed values within the BM800:

Baud rate = 19200 (9600 can be chosen)

 $\begin{array}{ll} Bits & = 8 \\ Parity & = None \\ Start/Stop \ bits = 1 \end{array}$

9.

PC Computer using a 25 pin RS232

| Cable end BM800 9 Pin Female DSUB | Cable end 'standard' PC 25 Pin Female DSUB |
|--------------------------------------|---|
| 23 | v |
| 5 | 7 |
| 7 | • |

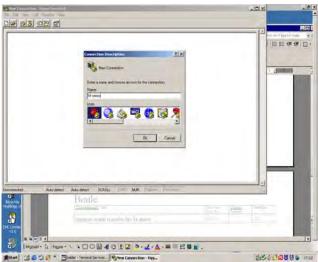
9.2.2 Establish a connection with Hyper terminal

In older generation of BM800 instruments with non USB port it is possible to establish a connection to hyper terminal. This to understand that instrument can send data through RS232 serial port properly.

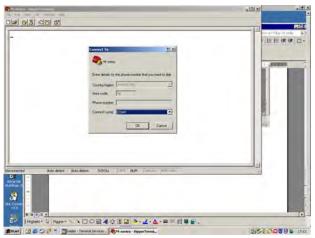
This connection is also needed for software upgrade, as old generation of BM800 do not have any USB ports Note. Vista, Win 7 and Win 8 does not have hyper terminal as default but can downloaded from internet free of charge.

Connect the serial cable on the instrument D-sub and PC D-sub. Start the hyper terminal program. It is available at Programs—Accessories—Communications

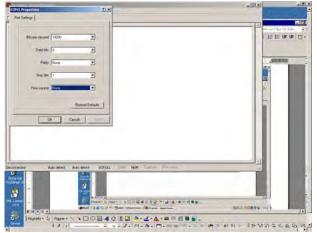




Choose a name for your setup



Choose the serial port that you have connected the instrument to.

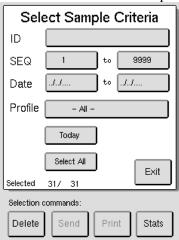


Choose the 'bits per second' [19200], 'flow control' [none] and then press [OK].

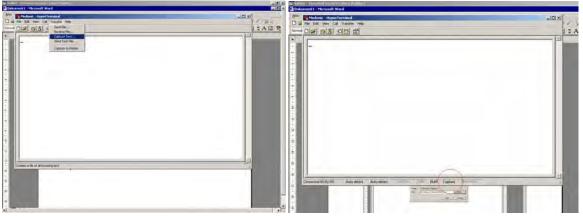
To determine if the connection is successful press <enter> and a '%' will pop up in the terminal screen.

9.2.3 How to transfer patient results from BM800 instrument in to a file

On BM800 choose the samples that you want to send from [SEARCH] in List menu.

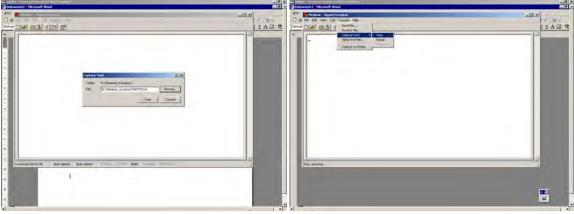


When the samples are chosen the actual samples will be displayed in Selected field and then [Send] button will be activated. After Send button is pressed then selected samples will be transferred To "Hyper terminal" on your computer as shown below



1. Choose (Transfer) and (Capture text)

3. Make sure "capture text is activated. Press (Send) on BM800 instrument. Now result Will appear on screen, wait until all selected Have been transferred.



Choose where you want to save the file. Make sure that the file name ends with.txt.

4. Then stop the file by choosing (Stop) from transfer menu. Now the file should have been Saved to your computer.

9.2.4 Hyper terminal Software upgrade

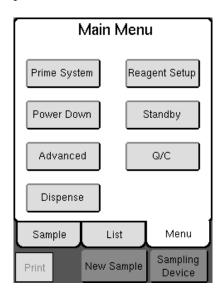
Make sure Hyper terminal connection is established as in 9.2.2

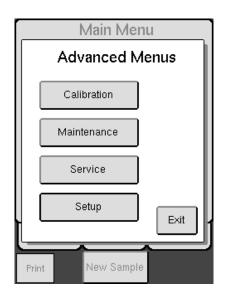
Before software upgrade in non USB instrument, correct software file needs to be downloaded from our support web page. This file is named mainboard-rom-x,x,x,hs/hw/hn, x,x,x stands for revision number like 2.9.2, **hs** stands for eastern language and **hw** stands for western language.

Both hs and hw version have English language available. Nordic language will be present on hn version. Download latest requested mainboard file from support web page and save it to your laptop or pen drive, this file will be used for hyper terminal software upgrade.

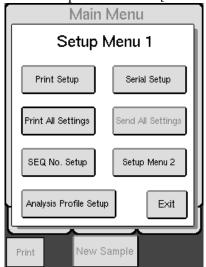
Note. During software upgrade sample memory can be erased, this will automatically be done depending from which version the software update is done from, inform customer before upgrade.

Before software upgrade we recommend to perform Print all settings, this to ensure if some settings will be changed during software upgrade Not possible to take any result backup to be restored after upgrade procedure.





In the Setup menu choose [Print all settings].



Start to upgrade program

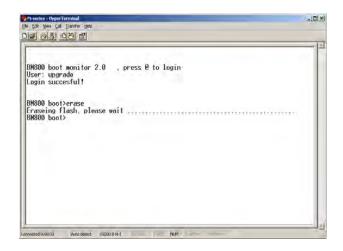
The following two steps need to be performed with in a 10 second range, if not completed within this time range initialization will start (if so restart from this point).

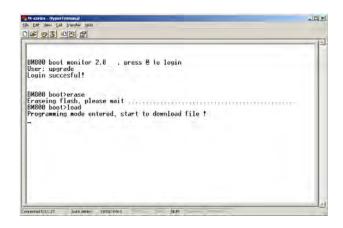
At the '%' type 'restart' and <enter>. Press '@' and <enter> when the instrument instructs you to. After you have pressed '@' the instrument prompts for a User. Type 'upgrade' and <enter>. The instrument will respond with the 'login successful' greeting and a BM800 prompt.

Type 'erase' followed by <enter>. Now the program memory is being erased, when the prompt reappears then the operation is completed. Note: The erase operation can take a few minutes. (After the completion of the operation, the memory is cleared and the instrument can now be loaded with a new or the previous software version to function. A download must be performed before the instrument will function.)

Type 'load' followed by <enter>.







The instrument is now ready to receive the upgrade file. DO NOT type anything in the terminal window (pressing the keyboard), instead browse your upgrade file using the menu option [Transfer] and [Send text file]. Choose the upgrade file from where you have saved it.

Note: Make sure that the box 'Files of type' has 'All files' selected. If not your *.xx file will not be displayed.



When the file is selected, and the [Open] button is pressed, the file download starts. A cursor will start to rotate in the terminal screen. It will take about 15-30 minutes.

Make sure that neither the PC nor the instrument is activated in any way.

When the download is completed, the instrument will automatically start the upgraded software.

Configure after update

After the software upgrade the Valve board and display board **might** need to be upgraded. The instrument will in those cases display a picture which gives the option to [Upgrade] or to [Skip], choose **Upgrade**. **Make sure to NOT touch the display during the upgrade of the valve or display board**.

Make sure that your shear valve positions and calibration factors are according to the 'Print all settings' printout. Also check other customer adjusted setups.

9.2.5 Problem solution during Hyper terminal upgrade

If there is a power lose during the upgrade

If the board has been 'erased' start from 9.2.3 and perform all the steps again.

If the 'erase' has not been performed the instrument is still in standard analyzing mode. Restart from 3.1.

If the display is touched during the software upgrade Restart from 9.2.3

If the cursor stops to rotate Restart from 9.2.3

If there is a loss of communication with the valve board after a successful software upgrade In terminal screen type 'board reflash v'

If there is a loss of communication with the display board after a successful software upgrade In terminal screen type 'board reflash d'

If not solved remove the power supply cable to dispay board, wait 60s connect the power cable, type 'board reflash d'

Notes:

Typing 'help' at the 'BM800 boot' prompt will give a short list of available commands. Typing 'log' will display possible errors.

Possible error messages are listed below:

| Error Code # | Text | Description/cause | |
|--------------|-------------------------------|---|--|
| 001 | System halted | The application start point could not be validated. This check is performed after reset and/or after completed downloads. | |
| 002 | Download failure, aborting | Below checks can be generated during download - A line in the upgrade file has a faulty CRC. - Missing or bad sections - Validation key is bogus, e.g. length is out of range - "Write" address points outside of application code area | |
| 003 | FLASH is not erased, aborting | A location in the flash memory has not been erased prior to programming. Download will be aborted. | |
| 004 | System failure | Internal error, receive buffer overrun | |
| 005 | FLASH malfunction | Internal error, flash memory is not responding to an erase or program operation | |
| 006 | System subcomponent failure | Internal HW error, no communication with the PIC subcomponent or the PIC subcomponent version is not supported | |

| Boule | Page14/18 |
|-----------------------------------|----------------------|
| Service manual BM800 Doc No 01959 | Section 9 Version 05 |

9.3 USB Software upgrade

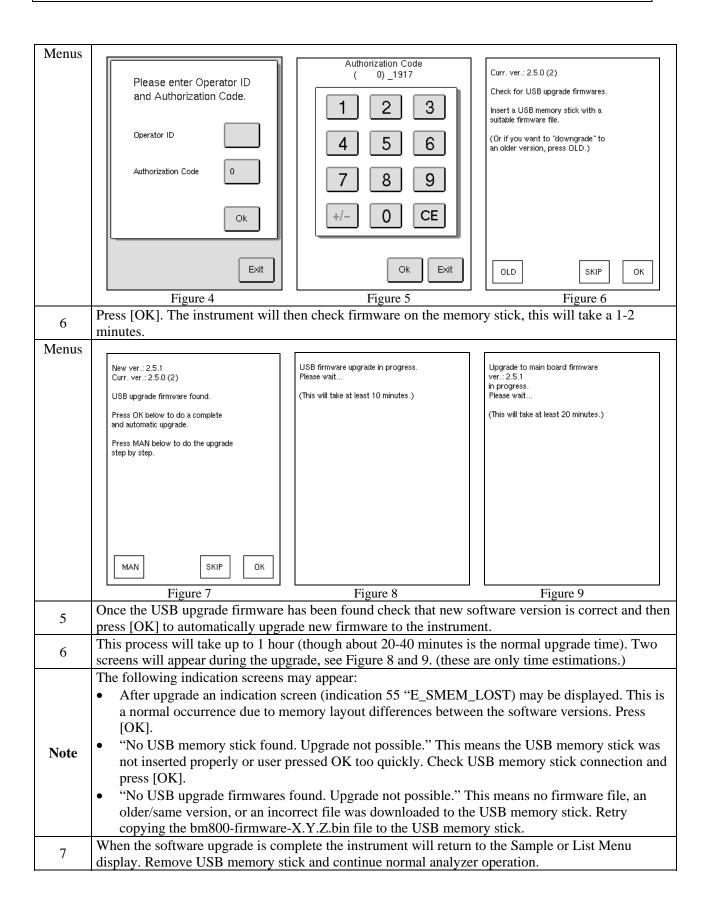
In BM800 instruments with USB ports available, software upgrade **must** be done from USB pen drive. (Not possible to perform from hyper terminal in USB instruments)

Download latest USB firmware from Boule support web page. The file will be named bm800-firmware x.x.x, where x.x.x stands for latest software version like 2.9.2. Extract the zip folder where this file is present in and save the file direct to a USB pen drive. Before USB firmware upgrade we recommend to perform Print all settings, see screen shots in section 9.2.4 above.

Sample memory can be erased during software update, inform customer before upgrade.

Not possible to take any result backup to be restored after upgrade procedure.

| Step | Action | | |
|-------|--|--|--|
| 1 | Copy the latest bm800-firmware-x.x.x.bin file to the USB memory stick. | | |
| Note | The following is recommended prior to starting upgrade: Remove all other bm800-firmware files from the USB memory stick. This speeds up the version checking. Use a narrow USB memory stick for upgrade. If wider USB memory stick is used, place in right-hand side of USB port, not directly underneath electronic reagent connectors. Software upgrade may erase patient sample memory. Operator may want to printout or | | |
| 2 | download patient sample results if not yet externally recorded. | | |
| 3 | Insert USB memory stick into USB memory port on rear panel of analyzer. Start upgrade by pressing [ADVANCED] from the MENU tab. | | |
| 4 | Press [SERVICE], [CONFIGURATION] and then [USB FIRMWARE UPGRADE]. | | |
| Menus | Main Menu Service Menu Calibration Calibration Maintenance Instrument Log Flush shear valve Service Menu 2 Figure 1 Figure 2 Figure 3 | | |
| 5 | An authorized operator needs to input the authorization code to upgrade new software version. Press Authorization Code button, enter in code [1917] or [3819] and press [OK] twice to accept. No need for any Operator id. | | |



9.4 Problem solutions during USB upgrade

9.4.1 Normal complete upgrade to newer version from USB memory stick:

- 1. We recommend removing all other bm800-firmware files from the USB memory stick. This speeds up the version checking
- 2. Copy the bm800-firmware-X.Y.Z.bin file you wish to use to the USB memory stick
- 3. Insert USB memory stick in 800
- 4. Go to "Advanced: Service: Configuration: USB Firmware Upgrade".
- 5. Enter code 1917. (The service code and the Boule code works too.)
- 6. Display "Check for USB upgrade firmwares". Press OK.
- 7. Wait
- 8. Display "USB upgrade firmware found". Check that "new version" is the version you wish to use. Press OK.
- 9. Wait (up to 1 hour). (Note: display says at least 10 minutes, but this is only the USB subsystem application upgrade time.)
- 10. If you get indication 55 "E_SMEM_LOST", the sample memory had to be cleared due to memory layout differences between the versions. Press OK.

9.4.2 Downgrade to older version from USB memory stick:

- 1. Remove all bm800-firmware files from the USB memory stick. Downgrading is blocked if there are bm800-firmware files with newer versions on the USB memory stick.
- 2. Copy the bm800-firmware-X.Y.Z.bin file you wish to use to the USB memory stick
- 3. Insert USB memory stick in 800
- 4. Go to "Advanced : Service : Configuration : USB Firmware Upgrade".
- 5. Enter code 1917. (The service code and the Boule code works too.)
- 6. Display "Check for USB upgrade firmwares". Press OLD.
- 7. Wait
- 8. Display "USB upgrade firmware found". Check that "old version" is the version you wish to use. Press OK.
- 9. Wait (up to 1 hour). (Note: display says at least 10 minutes, but this is only the USB subsystem application upgrade time.)
- 10. If you get indication 55 "E_SMEM_LOST", the sample memory had to be cleared due to memory layout differences between the versions. Press OK.

9.4.3 Step-by-step upgrade to newer version from USB memory stick

- 1. We recommend removing all other bm800-firmware files from the USB memory stick. This speeds up the version checking
- 2. Copy the bm800-firmware-X.Y.Z.bin file you wish to use to the USB memory stick
- 3. Insert USB memory stick in 800
- 4. Go to "Advanced: Service: Configuration: USB Firmware Upgrade".
- 5. Enter code 1917. (The service code and the Boule code works too.)
- 6. Display "Check for USB upgrade firmwares". Press OK.
- 7. Wait
- 8. Display "USB upgrade firmware found". Check that "new version" is the version you wish to use. Press MAN.
- 9. Wait (up to 20 minutes).
- 10. Display "Press OK to restart USB subsystem". Press OK.
- 11. Wait (up to 2 minutes)
- 12. Display "Press OK to restart instrument". Press OK.
- 13. Wait (up to 2 minutes)
- 14. Display "Main board upgrade firmware found". (If the main board firmware actually is unchanged, steps 14-23 are skipped.)
- 15 Press OK to do a complete firmware upgrade of the mainboard and sub board applications. Step 18-23 are skipped.
- 16 Press MAN to do a step-by-step upgrade of the mainboard and sub board applications.
- 17 Wait (up to 45 minutes)
- 18. The 800 asks about upgrading display board firmware. Press UPGR. (If the display board firmware actually is unchanged, steps 18-19 are skipped.)
- 19. Wait until display board firmware upgrade finished. (Note: display switches off during upgrade). Press OK.
- 20. The 800 asks about upgrading valve board firmware. Press UPGR. (If the valve board firmware actually is unchanged, steps 20-21 are skipped.)
- 21. Wait until valve board firmware upgrade finished. Press OK.
- 22. The 800 asks about upgrading cap piercer / sampler board firmware. Press UPGR. (If the cap piercer / sampler board firmware actually is unchanged, or if the 800 doesn't have any, steps 22-23 are skipped.)
- 23. Wait until cap piercer / sampler board firmware upgrade finished. Press OK.
- 24 If you get indication 55 "E_SMEM_LOST", the sample memory had to be cleared due to memory layout differences between the versions. Press OK.

9.4.4 Recover from lost main board application

- 0. The 800 indicates this situation by beeping Long-Long-Short-Pause 3 times after power on.
- 1. Put a file with the name mainboard-rom-recover.txt on a USB memory stick. (The content of the files does not matter. It can be empty.)
- 2. Switch off 800.
- 3. Insert USB memory stick in 800.
- 4. Switch on 800.
- 5. The 800 indicates this situation again by beeping Long-Long-Short-Pause 3 times after power on
- 6. After 20 50 seconds, the 800 indicates start of mainboard recovery with 3 short beeps.
- 7. Wait (up to 45 minutes)
- 8. The main board application should start. Clear any indications.
- 9. Switch off 800.
- 10. remove USB memory stick from 800
- 11. Wait 5 seconds
- 12. Switch on 800.
- 13. The 800 should start without indications

9.4.5 Recover from lost USB subsystem application

- 0. The 800 indicates this situation with indication 48 "E USB TIMEOUT" 80 100 seconds after power on.
- 1. Copy the bm800-firmware-uncompr-X.Y.Z.bin file you wish to use to the USB memory stick.
- 2. Rename the bm800-firmware file to bm800-firmware-rescue.bin
- 3. Switch off 800.
- 4. Insert USB memory stick in 800.
- 4. Switch on 800.
- 5. The 800 indicates this situation again with indication 48 "E USB TIMEOUT" 80 100 seconds after power on. Press OK. (If not, the 800 does not show indication 192 "E_USB_RESTARTED" below!)
- 6. Wait (up to 20 minutes).
- 7. The 800 shows indication 193 "E_USB_RESTARTED" when the USB susbsystem application has started.
- 8. Switch off 800.
- 9. remove USB memory stick from 800
- 10. Wait 5 seconds
- 11. Switch on 800.
- 12. The 800 should start without indications
- 13. If the 800 shows "Main board upgrade firmware found". Press OK. (If the main board firmware actually is unchanged, steps 13-14 are skipped.)
- 14 Wait (up to 45 minutes)
- 15 If you get indication 55 "E_SMEM_LOST", the sample memory had to be cleared due to memory layout differences between the versions. Press OK.

9.4.6 Recovery from lost display board application

- 0. The 800 indicates this situation by beeping Short-Long-Short continuously after power on. Note: this beep pattern indicates some kind of display board failure. Lost display board application is only one of these failures and the only one where this recovery procedure works.
- 1. Press the OT start plate behind needle and hold it pressed for 7-8 sec
- 2. When a short beep will appear, immediately release start plate
- 3. After 30-60 sec display should light up.
- 4. Press upgrade if this option appear otherwise power off and on instrument

Section overview

| 10. | General failure analysis (V02) | 2 |
|-----|--------------------------------|---|
| | HGB and/or WBC instability | |
| | MCV instability | |
| | WBC instability | |
| | RBC instability | |
| | PLT instability | |

10. General failure analysis (V02)

Failure analysis on any parameter within the hematology system requires some basic understanding on how parameters are related and the system flow procedure as described in Section 2 of this manual. This section must be read and fully understood by the service staff.

The basic measured parameters in any hematology system are always:

RBC

MCV

HGB

WBC

PLT

MPV

All other parameters like HCT and MCHC are derived from the above. In other words, an instability reported on HCT should be analyzed on whether this is caused by the MCV or the RBC parameter. Also, instable MCHC must be analyzed to trace the source to RBC, MCV or HGB, as these are the basic measured parameters.

As the BM800 contains a sequential diluting system, a failure in the first diluting step will result in both RBC, PLT, WBC and HGB instability. It is therefore of great importance to determine in which part of the system the failure is expected. Therefore any parameter failure in respect to reproducibility should be checked using the following procedure:

- 1. Use fresh human blood or a Boule control and perform a series of at least 10 runs using that sample.
- 2. Use the RBC and HGB parameters first and put them in table form.
- 3. Determine if there is a valid correlation between these 2 parameters.

Example:

| RBC | HGB |
|------|--|
| 4.56 | 14.5 |
| 4.95 | 14.9 |
| 4.40 | 14.3 |
| 4.6 | 14.5 |
| 4.7 | 14.7 |
| 4.87 | 14.9 |
| 4.41 | 14.4 |
| 5.01 | 14.9 |
| 4.32 | 14.3 |
| 4.52 | 14.4 |
| | 4.56 4.95 4.40 4.6 4.7 4.87 4.41 5.01 4.32 |

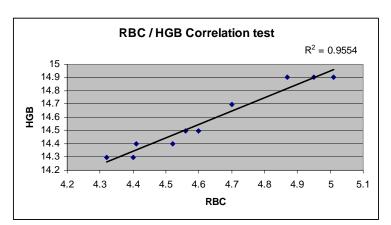


Figure 10.1

Using an XL worksheet, a correlation is found of R2 > 0.9. Hence, the conclusion is that the instrument failure is related to the first dilution step, which leads to the following possible errors:

- a. Bad blood aspiration (clogging in the blood aspiration inlet)
- b. Clogging in the shear valve separation channels
- c. First dilution failure in the primary mixing cup

The reason that RBC and HGB only in this first step is that these parameters have always the highest (best) statistical significance in hematology systems.

We might state that if the correlation of R2 > 0.6 there is statistical significance of a failure in the system.

In case there is no PC or laptop available to enter the data shown in Figure 10.1 above, a piece of paper is enough to achieve almost the same result.

Put the HGB and RBC on the Y-axis left and right, choose proper min/max scales that match the data to be entered. Use the X-axis to identify the sample ID. Draw lines between the measured data points. See example below:

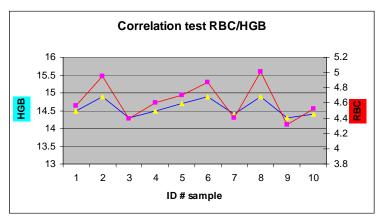


Figure 10.2

In Figure 10.2 a clear correlation is 'seen' without calculating the actual 'R' value . Hence, it gives us the same outcome and conclusion.

10.1 HGB and/or WBC instability

If an HGB instability is reported, check if any of the other parameters are instable as well by following the correlation test procedure as outlined in above. If no correlation with RBC is found, put the WBC and HGB values in a worksheet instead and determine the R2. In case of a valid correlation, the failure is NOT related directly to HGB but to the second dilution in the WBC counting chamber.

Valid correlation:

- a. Check the filling/emptying of the counting chamber MC2.
- b. Check DIS2 pipette filling and dispensing.

10.2 MCV instability

If a MCV instability is reported, check if any of the other parameters are instable as well by first testing the system on fresh drawn venous blood sample. The CV of the MCV should be less than 1 % within the normal range and typical less than 0.5%. A MCV instability will automatically influence the HCT and MCHC parameters as well.

In almost all cases, a MCV instability can be caused by only a few system failures:

- a. Contaminated Diluent
- c. Failure in the RBC orifice (located at MC1)

It is very unlikely that the error is caused by the electronic part of the system.

10.3 WBC instability

Follow the correlation test procedure as outlined in Section 10 above. If no correlation is found with the RBC and/or HGB parameter, proceed as follows:

Check the size-distribution curve of the WBC parameter. If it is shifted far to the left, no reproducible results will be possible.

This might be caused by:

- a. Bad lyse
- b. Failure in the WBC orifice (located in MC2)
- c. Electronic line interference

10.4 RBC instability

If a RBC instability is reported, check if any of the other related parameters are instable as well by following the correlation test procedure as outlined in Section 10 above.

If no correlation with HGB is found, the failure might be located in:

- a. Mixing chamber PM contamination or electrode failure within PM.
- b. Metering unit M1 not reproducible due to liquid drops or start-stop optical detector failure.

| Boule | Page 5/5 |
|-----------------------------------|-----------------------|
| Service manual BM800 Doc No 01959 | Section 10 Version 02 |

10.5 PLT instability

If a PLT instability is reported, check if any of the other parameters are instable as well by following the correlation test procedure as outlined in Section 10 above.

If no correlation with RBC is found, the failure may be located in:

- a. Contaminated Diluent (high background count)
- b. Mains-supply interference noise
- c. Failure in RBC orifice (MC1)
- d. Contaminated system

| Boule | Page 1/3 |
|-----------------------------------|-----------------------|
| Service manual BM800 Doc No 01959 | Section 11 Version 06 |

| 11. | Maintenance schedule (V06)2 | , |
|------|-----------------------------|---|
| | General schedule2 | |
| 11.2 | Service protocol BM8003 | |

| Boule | Page 2/3 |
|-----------------------------------|-----------------------|
| Service manual BM800 Doc No 01959 | Section 11 Version 06 |

11. Maintenance schedule (V06)

Maintenance of the BM800 should be carried out according to the schedule and in the noted order as provided in this section. The schedule assumes a working load of <100 samples/day. In case of higher work load, adjust the time-frames accordingly.

11.1 General schedule

| Service point | Procedure | Yearly, or >20.000samples | Every other year |
|--|---|---------------------------|---------------------|
| 1. Boule Cleaning kit* 1504111 | See instruction sheet inside cleaning kit | X | X |
| 2. PUMP P+ | 6.1 Check Pressure | X | X |
| 3. PUMP P- lower | 6.2.1 Check vacuum | X | X |
| 4. PUMP P- upper | 6.2.2 Check vacuum | X | X |
| 5. Premix cup | 6.5 Clean/check | X | X |
| 6. Back Flush Shear Valve | Clean aspiration path As shown in 6.7 | X | X |
| 7. Repair kit Waste Pump 1150521 | 6.2.3 Check/replace | Recommended to re year | eplace every second |
| 8. Fluid filter 2 x 1091161_S | Clean/replace | X | X |
| 9. Air pump/Filter 1141392_S for AC pump 1141398 for DC pump | Clean/replace | X | X |
| 10. MPA / MCI O-ring (O-ring 3,0 x 1,0) 1140626 | Clean MPA / MCI, replace O-ring | X | X |
| 11. Waste tube 1090028 | Replace | X | X |
| 12. Photometer HGB | 6.4 Check/adjust | X | X |
| 13. Open tube aspiration needle/tubing 1091152_S | Clean/replace | X | X |
| 14. Silicon tubing's inside valves 9970002 | Check/Replace every second year | X | X |
| Specific CAP instrument | | | |
| 1. CAP needle 1091352_S | 4.1.2 Remove needle and clean with hypochlorite | X | X |
| 2. Tubing kit 24 CAP 1091171_S | 4.2.3 Replace | X | X |
| 3. Wash cup/Sleeve assy 1021055_S | 4.2.2 Clean/replace | X | X |

- See also user manual section 8 regarding operator maintenance procedures.
- Silicon tubing inside valves is only recommended to replace if they are pinched or damaged due to a high number of analyses, recommendation would be to replace after 2-3years
- See suggested service protocol below which can be used as a template

| 11.2 Service protocol BM800 | | | |
|--|---------------------------|--|--|
| | Snr: Software | | |
| Clinic | | | |
| | Reference | | |
| Notice before maintenance | | | |
| Notice before maintenance | | | |
| | | | |
| | | | |
| Cleaning | Check/Adjustment | | |
| 1.Cleaning kit 1504111 | 11.HGB adjust | | |
| 2.Backflush Shear valve | 12.Start/Stop detectors | | |
| 3.Mixing beaker | 13.Blood detector | | |
| 4.MPA | 14.Mix beaker detectors | | |
| 5.CT Module | 15.RBC/WBC counting time | | |
| | 16.Noise test | | |
| Check/Exchange | Function check | | |
| 6.Repairkit Waste pump | 17.MPA | | |
| 7.Silicontubings | 18.CT Module | | |
| 8.Other tubing's | 19.P- Waste pump>500 mbar | | |
| 9.Oring MPA | 20.P Waste pump>500 mbar | | |
| 10.CT Needle | 21.P+ Air pump>250 mbar | | |
| | 22.Electromagneticvalves | | |
| Check/Perform | Check/Perform | | |
| 22.Background | 24.Calibration MPA | | |
| 23.Calibration Whole blood | 25.Calibration Predil | | |
| X=Done E=Exchange A=Adjusted Cl=Clean CH=Checked= Not applicable | | | |
| Notes | | | |
| | | | |
| | | | |
| Service Technican | Date | | |

| 12. Sche | ematics (V03) | 2 |
|----------|-------------------------|----|
| 12.1 PC | CB description | 4 |
| 12.1.1 | PCB communication | 4 |
| 12.1.2 | CPU board | 4 |
| 12.1.3 | CPU 00169 | 7 |
| | Power supply 0235 | |
| 12.1.5 | Display 00215 | 11 |
| | Valve drivers 00204 | |
| 12.1.7 | Level detectors 00323 | 13 |
| 12.1.8 | Cap Piercing unit 01055 | 14 |
| 12.1.9 | Sampler unit 00975 | 15 |

12. Schematics (V03)

Note:

Potentiometer positions should never be changed without written instructions from Boule.

Written instructions are defined as:

- Procedures on how to change PCBs
- Technical bulletins

Refer to Section 6 whenever changing the CPU PCB and check Section 15 for additional information when applicable.

Several PCBs are used in the BM800. The functionality of each is listed below. Veterinary instrument do not have option like Cap or Sampler PCB otherwise it is similar structure.

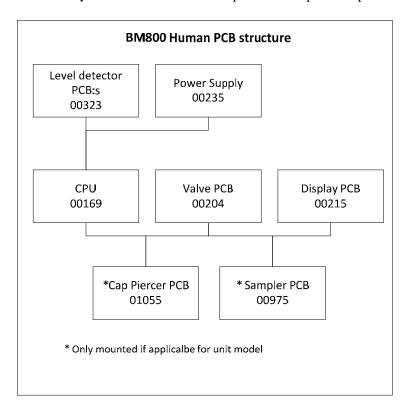


Figure 12.1

Identification of the PCBs is done by means of printed numbers on the layout. Hence, the Power supply board is marked as 00235-x, where x is the version number. The version number is essential for backtracking purposes as well as compatibility issues in previous and/or future versions. Section 6 might contain special procedures how to change PCBs with references to the version number(s).

Listed below is the complete BM800 PCB identification structure:

| PCB type | Schematics number | *PCB copper number | PCB complete |
|----------------|-------------------|--------------------|--------------|
| Power Supply | 00233 | 00234 | 00235 |
| Display | 00213 | 00214 | 00215 |
| CPU | 00171 | 00170 | 00169 |
| Valve | 00202 | 00203 | 00204 |
| Level detector | 00322 | **00323 | **N.A. |
| Cap Piercer | 01053 | 01054 | 01055 |
| Sampler | 00973 | 00974 | 00975 |

^{*} Only for internal use at Boule

As an example, refer to Figure 12.2 below which shows the identification number (00169) and version number (07) of the CPU PCB, always printed on the component side.

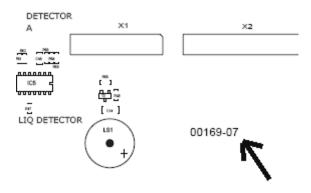


Figure 12.2

Notes:

- The level detector PCB 00323 has no component layout as the detector cells are mounted separately. Hence, the detector is not a part of the PCB.
- In case of PCB post-production modifications, the PCB has an additional marker which is referred to in a technical bulletin listed in Section 15.
- Spare part numbers are not the same as PCB identification numbers. Refer to Section 13 for a full description of spare part numbering and ordering.

^{**} See 'Notes' below

12.1 PCB description

This chapter describes the functions of all PCBs used in the BM800. Detailed component trouble shooting is not described as most PCBs are equipped with surface mounted technology and therefore not subject to detail repair at the distributor site. One exception might be the analogue power supply which is less complex and possible to measure/repair at site.

12.1.1 PCB communication

The PCBs are connected via a CAN bus cables (Controller Area Network). Hence, the CPU software sends commands over this bus to each separate PCB. This keeps the wiring to a minimum in the system. It is therefore obvious that the software loaded in the CPU PCB not only contains the application but also important processes necessary to operate the system. It is not required for service purposes to learn/understand the underlying functions of the used protocol.

12.1.2 **CPU** board

During the years we have released 3 versions of CPU board in BM800 instrument.

- First generation of CPU board is used in human instrument from serial number **10100** to **12999**. This board has RS232 serial and parallel port for data and printer connectivity but no USB port available. See Figure 12.3. Software upgrade for this board must be done through external pc and hyper terminal. See service manual chapter 9.2 for software upgrade procedure.
- Second generation of CPU board was used for both human and veterinary instruments. This board had RS232, parallel and USB port available. See Figure 12.4. This board was used in human instrument from serial number 13000 and above, this board was also used in early generation of our veterinary model (not Eos). Today this board has been replaced with third generation and is no longer available as spare part.
- Third generation of CPU board was introduced during end of 2011. This board has only USB ports available for barcode, computer and printer communication. See Figure 12.5. Article number for this board is 1091373_S for human and 1091394_S for veterinary instruments. This board can be used in human instrument with serial number **above 13000 and in all veterinary instruments**. Software upgrade for these boards must be done from USB port with a pen drive, see service manual chapter 9.4 for software upgrade procedure.

See pictures in following page to identify these boards.



Figure 12.3, 1091305_S, CPU board, RS232, parallel port used in snr: below 13000





Figure 12.4 1091318_S (Human) and 1091317_S (Vet)

10913173_S (Human) and 1091394_S (Vet)

Figure 12.5

(This board is not available anymore)

(This version is used in snr: above 13000 and in all Vet)

In case CPU board replacement in older generation of instrument is needed below option is available.

- Human Instrument with serial number 10100 to 12999 should still use non USB CPU board 1091305_S, this board is available as spare part.
- Human Instrument with serial number 13000 and above should use 1091373_S, CPU board USB and all Veterinary instrument should use 1091394_S CPU board USB.
- As new CPU board has only USB ports we can offer below accessories to support computer, barcode reader and printer connectivity. Note!! USB barcode readers and printers can be connected direct to CPU board, only configuration from setup menu could be needed.







1141463_S, RS232-USB converter

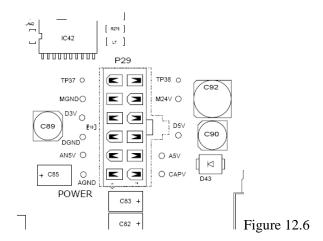


1141464_S, Parallel-USB printer cable

| Boule | Page 7/15 |
|-----------------------------------|-----------------------|
| Service manual BM800 Doc No 01959 | Section 12 Version 03 |

12.1.3 CPU 00169

The CPU PCB also contains the analogue amplifier for the RBC, WBC and HGB channel. Further measuring points for the power supply are found near the P29 connector. Figure 12.6 shows the test points for power supply voltages as described in Section 12.1.4. Use DGND as digital voltage reference and AGND for analogue voltages. MGND is the ground reference point for M24V. The voltage 'D5V' is equal to D5V_A in Section 12.1.4.



The analogue section of the CPU board is well separated from the digital part. The following test points/adjustments within the analogue system might be referred to in Section 6 'Changing PC Boards' whenever applicable.

| TP/ | Schematics | Instrument to be | Function | Comments |
|-------|---------------|------------------|--------------------|--|
| Comp. | | used | | |
| P30-1 | RBC amplifier | Scope/V-meter | Offset adj. Testp. | Used for failure analysis and adjustment |
| P30-3 | WBCamplifier | Scope/V-meter | Offset adj. Testp. | Used for failure analysis and adjustment |
| P30-2 | AGND | - | GND Reference | Analogue GND for all measurements |
| RV2 | Pot. meter | V-meter at P30-1 | Offset adj. RBC | Adjust 0.0mV (RBC coax disconnected) |
| RV1 | Pot. meter | V-meter at P30-3 | Offset adj. WBC | Adjust 0.0mV (WBC coax disconnected) |
| RV4 | Pot. meter | Scope at P30-1 | Gain adj. RBC | Scale adjustment RBC, MCV |
| RV3 | Pot. meter | Scope at P30-3 | Gain adj. WBC | Scale adjustment WBC, Gran peak |
| RV5 | Pot. meter | HGB service menu | Gain HGB | Blank range adjustment |
| | | | | |

The test point block P30 is mounted and numbered on the PCB layout as shown in Figure 12.7 below:

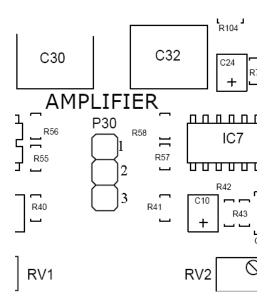
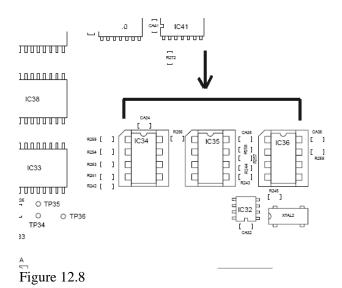


Figure 12.7

Some CPU ICs are specific for the instrument. The following IC positions, mounted in sockets, needs special attention and are a part of the PCB change procedure as described in Section 6. IC34 = HPC that has chassis number, model/type of instrument and other specific instrument settings programmed by Boule at the purchase of the unit.

IC35 = EEPROM that stores all user settable parameters like: calibration, reference ranges, discriminator settings etc. Shear valve calibration settings are also stored in these ICs. See Figure 12.8 below which points to these specific IC positions.



12.1.4 Power supply 0235

The power supply is an analogue system. In older generation of BM800 instruments, serial number 13000 and below a power transformer is used to create the necessary voltages which are rectified and stabilized. The power supply is dimensioned for all PCBs used in the BM800, including the optional cap piercer or sampler unit. In later generation of BM800 instruments with serial number 13000 and above, we use an external power supply which generates 24V DC in to instrument. This power supply can be supplied with 100-240V AC and 50-60Hz.

Figure 12.9 describes how old generation of power board supply voltage, snr: below 13000

Figure 12.10 describes how new generation of power board supply voltage, snr: above 13000 and in all veterinary instruments

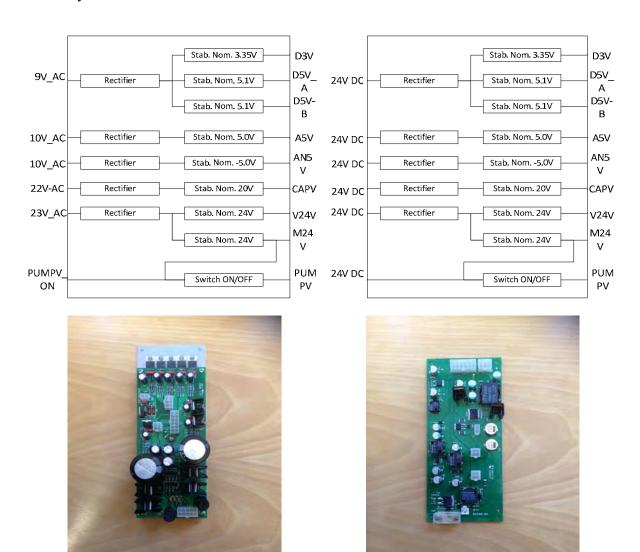


Figure 12.9, 1090939_S, Power board

Figure 12.10, 1120078_S, Switched PCB

Figure 12.11, below, shows a summary of the voltages used in the BM800. Currents are estimated with continuous operation of the system.

| Volt name | Voltage (nominal) | Current (mean) | Current (Peak, < 2 s) | Use |
|-----------|----------------------|----------------|-----------------------|----------------------------|
| D3V | 3.35 V | 0.3 A | 0.5 A | Digital electronics, 3.3 V |
| D5V_A | 5.1 V | 1.0 A | 1.9 A | Digital electronics, 5.0 V |
| D5V_B | 5.1 V | 1.5 A | 1.5 A | Digital electronics, 5.0 V |
| A5V | 5.0 V | 100 mA | 150 mA | Analogue electronics. |
| AN5V | - 5.0 V | 100 mA | 150 mA | Analogue electronics. |
| CAPV | 20.3 V | 15 mA | 50 mA | Orifice voltage |
| V24V | 24.1 V | 0.4 A | 3.2 A | Valves |
| M24V | 24.1 V | 0.4 A | 0.9 A | Motors |
| PUMPV | 24.1 V | 0.5 A | 0.6 A | Pumpmotor. |

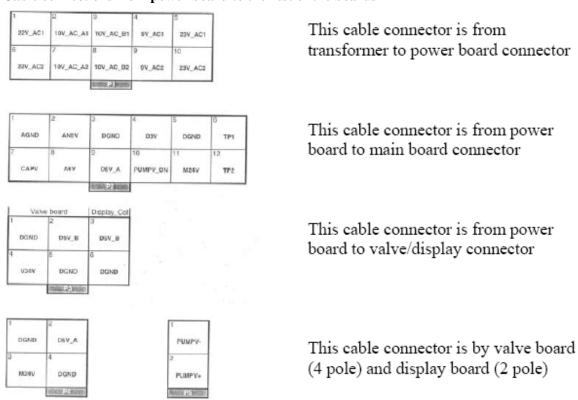
Figure 12.11

Voltage measuring points are not located on PCB 0235. Refer to the CPU PCB instead.

Note:

Voltage stabilizers D3V, D5V_A, D5V_B, V24V and M24V are mounted on heat sinks and are electrically isolated from the chassis.

Cable connections from power board to the rest of the boards



12.1.5 Display 00215

The display PCB is an interface board, connecting the actual display unit to the system CPU. It also contains a touch screen. Today we use a TFT color display. In older generation of instruments we used a FSTN or monochrome display. In older generation of display it was possible to adjust angle/intensity from a potentiometer located to the left front side of display. In new TFT display picture is clearer and brighter, in this model it is not possible to adjust any intensity. As display board is not compatible between old and new display, it is not possible to mount new TFT touch display together with old display board. In case old generation of display breaks down a replacement to complete TFT display needs to be done. To support touch screen for TFT display, software 2.6.7 or above must be installed in instrument. Touch screen function for TFT display works through small brown flat cable and interface communication between display board and screen works through the bigger white flat cable, see below. For non function of touch or display, check connections for these cables between the modules





Old generation of display (Not available anymore) 1091333 S TFT display replace old generation



Communication between touch screen and display PCB

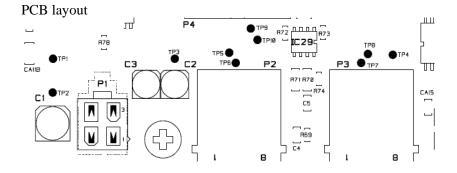
12.1.6 Valve drivers 00204

The valve driver board consists of identical drivers for the bi-stable valves. Note that no continuous current is used. To toggle a valve position from open to close or vice verse, a pulse is applied only. Today we have two different models of valve boards. 1090959_S Valve board is a shorter model and is used in human instruments from serial number 10100 to 12999. Valve board 1091370_S is a longer version of valve board and is used in human instruments from serial number 13000 and in all veterinary instruments.

Voltages on this board can be measured at the following points:

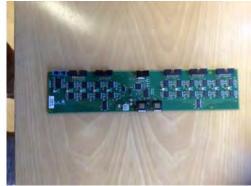
| TP | Schematics | Instrument to be | Function | Comments |
|---------|------------|------------------|------------------|---------------------------------|
| | | used | | |
| TP1/TP4 | DGND | V-meter | Ground reference | |
| TP2 | D5V | V-meter | Digital supply | Marked as D5V_B in power supply |
| TP3 | V24V | V-meter | Valve power | Voltage to valve & drivers |

Figure 12.12





1090959_S, Valve board (Serial number below 13000)



1091370_S, Valve board (Serial number above 13000 and all Vet instruments)

12.1.7 Level detectors 00323

The level detector(s) consist of a LED as a light transmitter and a phototransistor as a receiver. They are placed at a specific angle for maximum sensitivity. No test points are available. On air in a glass tube, the phototransistor receives maximum light intensity and therefore a low voltage (0.1V) is measured at the phototransistor collector. When filled with liquid, the angle of refraction changes and light is bended from the phototransistor, a high voltage (3.3V) is now measured at the phototransistor collector.

The LED current is automatically switched off during standby.



1091342_S, Level detector



Glass pipettes with detectors mounted

12.1.8 Cap Piercing unit 01055

The cap piercing electronics consists of motor drivers and input switch sensors. The system is controlled from the main CPU via the CAN bus.

Voltages on this board can be measured at the following points:

| TP | Schematics | Instrument to be used | Function | Comments |
|---------|------------|-----------------------|------------------|---------------------------------|
| TP1/TP4 | DGND | V-meter | Ground reference | |
| TP2 | D5V | V-meter | Digital supply | Marked as D5V_B in power supply |
| TP3 | M24V | V-meter | Motor power | Voltage to motors |

Figure 12.13

PCB Layout

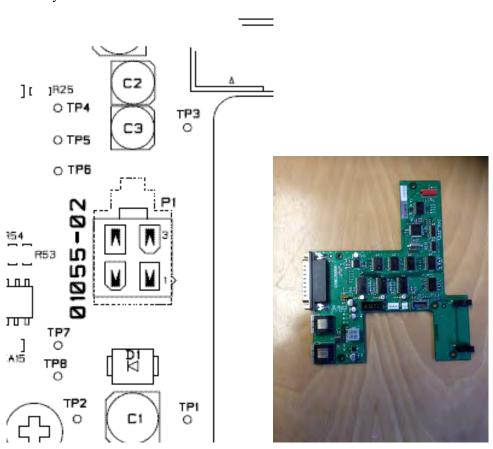


Figure 12.13

1120075_S, Cap board

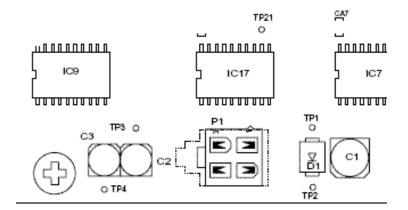
12.1.9 Sampler unit 00975

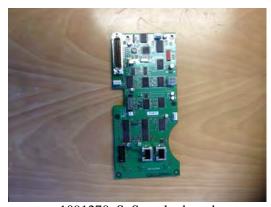
The sampler electronics consists of motor drivers and input switch sensors. The system is controlled from the main CPU via the CAN bus.

Voltages on this board can be measured at the following points:

| TP | Schematics | Instrument to be | Function | Comments |
|---------|------------|------------------|------------------|---------------------------------|
| | | used | | |
| TP1/TP4 | DGND | V-meter | Ground reference | |
| TP2 | D5V | V-meter | Digital supply | Marked as D5V_B in power supply |
| TP3 | M24V | V-meter | Motor power | Voltage to motors |

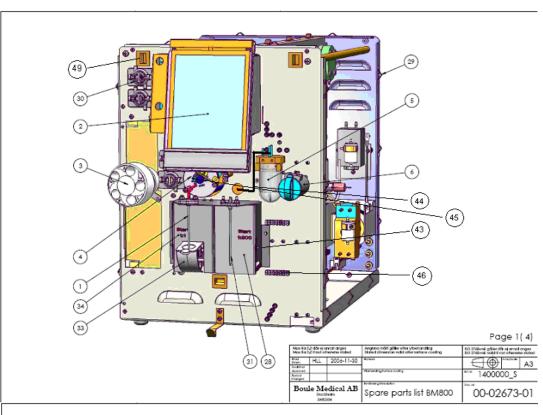
Figure 12.14

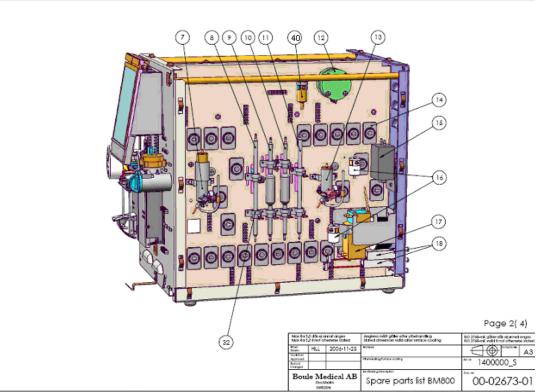


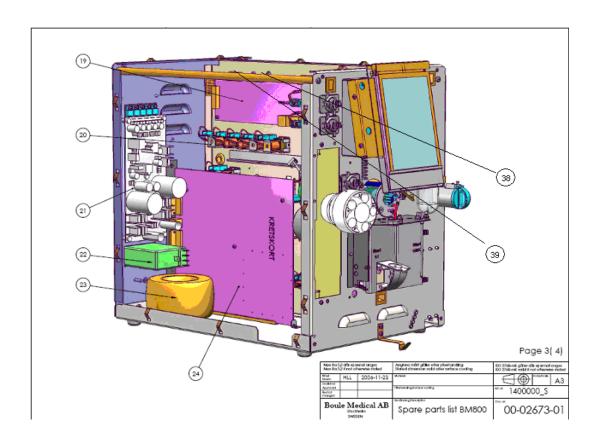


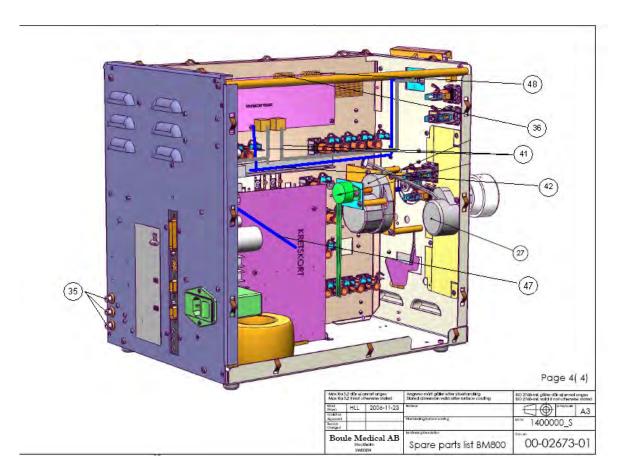
1091270_S, Sampler board

13.Spare part list (V09)





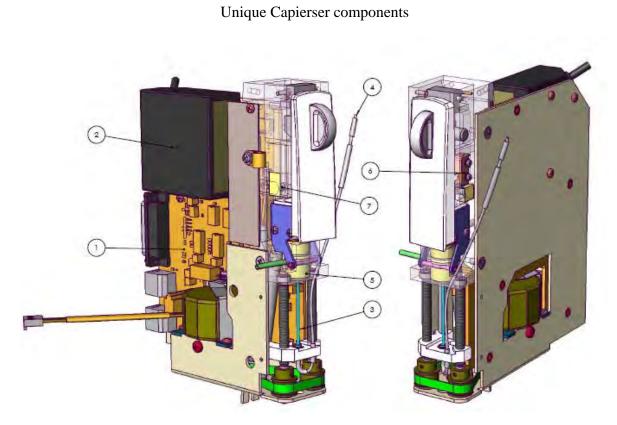




| Article number | Name | Position | Needs |
|----------------|--------------------------------|----------|-------|
| 1010853 S | Start plate washing cup | 34 | - |
| 1010854_S | Start plate PD | 28 | - |
| 1030116 S | Valve cable 1 | 39 | - |
| 1030117_S | Valve cable 2 | 38 | _ |
| 1030118_S | Valve cable 3 | 48 | _ |
| 1030119_S | Valve cable 4 | 36 | _ |
| 1030125 S | Cable, VD power Valve, Display | 42 | _ |
| 1030127_S | Power cord Main board | 47 | _ |
| 1030128_S | Cable blood detector | 45 | _ |
| 1030129 S | BB cable, Mixing chamber cable | 44 | |
| 1030140_S | Cable Coax WBC | 13.2 | _ |
| 1030142_S | Cable, photometer | 13.3 | 1 |
| 1030143_S | Ground cable | 13.3 | |
| 1040017 S | Contact plate cover ground x10 | 29 | |
| 1080055 | Tube holder | 46 | |
| 1090719_S | Switch cable MPA | 6.3 | |
| 1090719_S | Cable, Start Micro switch | 34.1 | 1 |
| 1090796_S | Switch | 34.1 | 1 |
| 1090790_S | Air Pump with bracket assay | 15 | 1 |
| 1090900_3 | Below serial nr: 13000 | 13 | 1 |
| 1141392_S | Filter Air-pump | 15 | _ |
| 11.10,2_0 | Below serial nr: 13000 | | |
| 1090910_S | Tube valve complete | 14,20 | 2 |
| 1080058_S | Pinch valve head x10 | 30 | 1 |
| 1060046 | Rubber Washer Tube valve | 30 | - |
| 1090914_S | Aspiration PD | 31 | - |
| 1091319 S | Membrane pump | 12 | - |
| 1091342_S | Level detector complete | 32 | 1 |
| 1091324_S | WBC measuring chamber complete | 13 | 1 |
| 1091165 S | Capillary holder WBC | 13.1 | - |
| 1091325_S | RBC measuring chamber Human | 7 | 1 |
| 1091141_S | Cap. Holder complete RBC | 7.4 | - |
| 1091286 | Cleaning unit complete | 43 | - |
| 1091308_S | Shear valve complete | 4 | 1 |
| 1091333_S | TFT Display complete | 2 | 1 |
| 1141426_S | TFT Touch display | 2.1 | - |
| 1091323_S | TFT Display board | 2.1 | - |
| 1141427_S | Flat cable TFT display | 2.1 | - |
| 1050424_S | Spacer bar old Display | 2.1 | |
| 1090931_S | MPA/MCI complete | 6 | 1 |
| | Serial nr: 10783 and below | | |
| 1091232_S | MPA/MCI complete | 6 | 1 |
| | Serial nr: 10784 and above | | |
| 1091227_S | MPA/MCI handle complete | 6.2 | - |
| 1090933_S | Asp. washing cup complete | 33 | |
| 1090941_S | Drain cup | 40 | - |
| 1090939_S | Power board complete BM800 | 21 | - |
| | Below serial nr: 13000 | | |
| | | | |
| | | | |

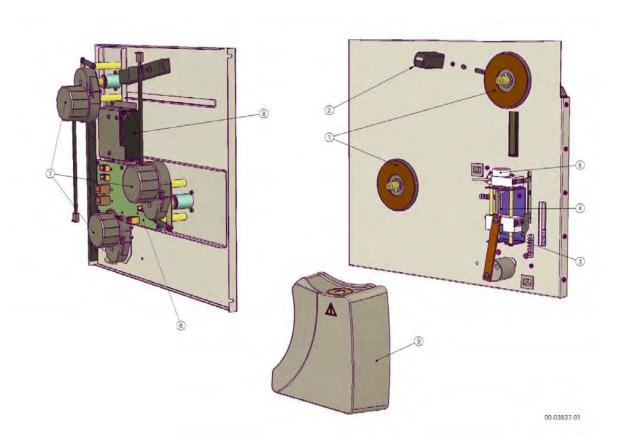
| Article number | Name | Position | Needs |
|----------------|---------------------------------------|----------|-------|
| 1090959_S | Valve board BM800 | 19 | - |
| | Below serial nr: 13000 | | |
| 1091305_S | CPU board non USB | 24 | 1 |
| | Below serial nr: 13000 | | |
| 1091034_S | Level detector, Diluent | | 1 |
| 1091035_S | Level detector, Lyse | | 1 |
| 1091043_S | RBC pipette incl. Tubes | 9 | - |
| 1091044_S | WBC metering unit incl. tubes | 11 | - |
| 1091045_S | Solenoid inlet valve 24V complete | 18 | 1 |
| 1091050_S | RBC metering unit incl. tubes | 8 | ı |
| 1091061_S | WBC pipette incl. Tubes | 10 | ı |
| 1091080_S | Barcode reader Datalogic RS232 incl. | | 1 |
| | Cable below serial nr: 17751 (Human), | | |
| 1001000 0 | 51501(Vet) 52251 (Vet Eos) | 1 | |
| 1091088_S | Kit, Reagent Connectors | 35 | - |
| 1091085_S | Mixer motor M-series | 27 | - |
| 1091086_S | Mixer motor Alfa and Exigo | 27 | - |
| 1091152_S | Aspiration whole blood | 1 | 1 |
| 1091161_S | Fluid filter assay | 16 | 2 |
| 1100022_S | Pipette 4,5 ml | 9, 10 | 1 |
| 1100023_S | Measuring Tube | 8, 11 | 1 |
| 1140142 | Fuse T 3,15 A (110 V) | 22.1 | - |
| 9990345 | Fuse T 5A | 21 | - |
| 1140392 | Fuse T 1,6A (240 V) | 22.1 | - |
| 1140626 | O-ring 3,0 x 1,0 Nitril | | 2 |
| 1140641 | Clips for door | 49 | - |
| 1140643_S | Transformer BM800 | 23 | - |
| | Below serial nr: 13000 | | |
| 1140645_S | Mains filter plug unit | 22 | - |
| | Below serial nr: 13000 | | |
| 1140703_S | Cable for CAN COM. 0,5m BM800 | 41 | - |
| 1141338 | O-ring 3,3 x 2,4 nitril | | - |
| 1150495_S | Waste pump | 17 | 1 |
| 1150521 | Repairkit Waste pump | | 2 |
| 5306026_S | Mixing cup complete | 5 | - |
| 5308009_S | Cable, coax, RBC, L=420 | 7.1 | - |
| 5814036 | Mixing cup | 5.1 | 1 |
| 9970001 | Tubing 1.0 x 3.0 Silicon | | 1 m |
| 9970002 | Tubing 1.5x3.0 Silicon | | 3 m |
| 9970005 | Tubing 2.0*5.0 Silicon | | - |
| 9970024 | Tubing 1.6*3.2 Teflon | | 1 m |
| 9970031 | Tubing 3.0x5.0 PVC | | 1 m |
| 9970119 | Tubing FEP 0.7 x 1.5 | | 1 m |
| 9970042 | Tubing Tygon 1.6 x 3.2 | | 1 m |
| 1090028 | Waste tubing | | 2 |
| 9990475 | O-ring 5.3x2.40 Silicon | | _ |
| 9990921 | O-ring 1.78* 1.02 viton | 7,13 | - |
| 9991085 | O-ring 13.10 x 1.60 Nitril | 7, 13 | - |
| 1504111 | Boule Cleaning Kit 3 x 450 ml | - | 2 |
| | | | |
| | | | |
| | | • | |

| A | N | D:4: | N 1- |
|----------------|--|----------|-------|
| Article number | Name | Position | Needs |
| | | | |
| 1001004 0 | Unique Swelab components | 1 1 | |
| 1091094_S | Front comp Swelab Sampler dev | | - |
| 1091095_S | Front complete Swelab mixer | | - |
| 1091096_S | Front comp Swelab CAP | | - |
| 1091151_S | Front comp Swelab Basic | | - |
| 1021111_S | Mixer Wheel Alfa | 3 | - |
| 1091086_S | Mixer motor complete Alfa | 27 | - |
| | | | |
| 1001004 G | Unique Medonic components | | |
| 1091084_S | Front Medonic mixer | | - |
| 1090998_S | Front Medonic CAP | | - |
| 1090999_S | Front Medonic Sampler | | - |
| 1091150_S | Front Medonic Basic | | - |
| 1021110_S | Mixer Wheel M-series | 3 | - |
| 1091085_S | Mixer motor complete M-series | 27 | - |
| | e instrument serial number 13000 and | | |
| 1091268_S | Air pump DC | 15 | 1 |
| 1141398 | DC-Air pump silencer/filter | 15 | - |
| 1091370_S | Valve board | 19 | 1 |
| 1141414_S | External power converter unit | | 1 |
| 1120078_S | Switched Power board | 21 | 1 |
| 1141368 | Power switch | | |
| 1091373_S | CPU board Human USB only | 24 | 1 |
| 1141462_S | USB cable for Data logic BCR | | |
| 1141463_S | RS232-USB converter cable | | |
| 1141464_S | Parallel-USB converter cable for printer | | |
| 1141495_S | Barcode reader USB | | 1 |
| | | | |
| | Unique Veterinary components | | |
| 1010921_S | Start plate VET | 34 | - |
| 1141414_S | External power convertor unit | | 1 |
| 1120078_S | Switched Power board | 21 | 1 |
| 1141368 | Power switch | | - |
| 1091271 | Front complete Exigo | | - |
| 1021159_S | Mixer wheel Exigo | 3 | - |
| 1030146 | Valve cable 5 | | - |
| 1091370_S | Valve board | 19 | 1 |
| 1091268_S | Air pump DC | 15 | 1 |
| 1141398 | DC-Air pump silencer/filter | 15 | - |
| 1091354_S | Level detector Red (Diluent) | | 1 |
| 1091353_S | Level detector Yellow (Lyse) | | 1 |
| 1091355_S | Level detector Blue (Cleaner) | | 1 |
| 1091356_S | Level detector Green (Eos) | | 1 |
| 1091367_S | Level detector 10L Exigo diluent | | 1 |
| 1091325_S | RBC measuring chamber VET 80um | 7 | 1 |
| 1091345_S | RBC measuring chamber VET Eos | 7 | 1 |
| | 60um | | |
| 1091394_S | CPU board VET USB ports only | 24 | 1 |
| 1141462_S | USB cable for Datalogic BCR | | |



| Unique Capierser components | | | | |
|-----------------------------|-------------------------------|----------|-------|--|
| Article number | Name | Position | Needs | |
| 1091112_S | CAP-Piercer assy without BCR | | - | |
| 1090975_S | CAP-Piercer assy with BCR | | 1 | |
| 1120075_S | CAP-board | 1 | 1 | |
| 1141467_S | Barcode reader internal (BCR) | 2 | - | |
| 1091352_S | Needle assy. CAP | 3 | 1 | |
| 1091171_S | Aspiration tubing CAP | 4 | 1 | |
| 1021055_S | Needle wash cup | 5 | 1 | |
| 1030136_S | Cable assy, start switch | 6 | 1 | |
| 1030137_S | Cable assy, tube sensor | 7 | 1 | |
| 1091321_S | Cap door | | | |

Unique Sampler components

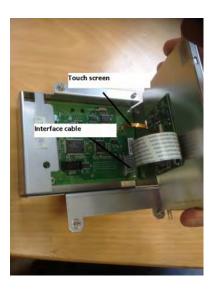


| Unique Sampler components | | | | |
|---------------------------|---------------------------------|----------|-------|--|
| Article number | Name | Position | Needs | |
| 1091293_S | Magnetic plate assy. | 1 | - | |
| 1091029_S | Tube detector | 2 | - | |
| 1091192_S | Aspiration tubing Sampler | - | 1 | |
| 1091437_S | Needle assy. Sampler | 4 | 1 | |
| 1090984_S | Washing cup assy. | 5 | - | |
| 1091270_S | Sampler board tested | 6 | 1 | |
| 1091225_S | Motor/Gear box needle and wheel | 7 | 1 | |
| 1141467_S | Barcode reader internal ABR | 8 | - | |
| 1091223_S | Sampler side cover assy. | 9 | - | |
| 1091322_S | Sampler ABR upgrade kit | | | |
| 1091357_S | Link arm needle movement | 3 | 1 | |

| 14. | Troub | leshooting and error guide | |
|-----|-------|---|----|
| | 14.1 | Display issues | 2 |
| | 14.2 | Valve board and valve issues | 2 |
| | 14.3 | Shear valve movement issues (Indication 71, 75) | 3 |
| | 14.4 | DP and DF error flag | 3 |
| | 14.5 | Aspiration failure AF flag OT and CT mode | 9 |
| | 14.6 | High PLT with SE or DE flag | 13 |
| | 14.7 | HL, HH and HF flag related to HGB | 14 |
| | 14.8 | TE flag | 16 |
| | 14.9 | TU and TL flag for RBC and WBC | 18 |
| | 14.10 | WBC, RBC and PLT DE flag | 20 |
| | 14.11 | WBC gain check with Boule control | 20 |
| | 14.12 | DE flag on Boule Control | 21 |
| | | | |

14.1 Display issues

If the green LED and the display light up but touch screen does not work, check the connection for brown flat cable to the display board. In case green LED light but not display, check blue power connector cable to the display and white flat cable between touch and display board.



In case display is black and you hear continually beeps try below.

- 1. Check CAN communication cable to display from valve board.
- 2. Press and hold start plate behind Open tube needle for 7-8 sec, if/when you hear a short beep then immediately release start plate and wait 60 sec to see if display lights up. After light up, reboot instrument and press upgrade button in case this option appears.
- 3. If problem persist replace display

If the green LED does not light up and display is black, then check power converter outside instrument that it works ok. In older units make sure that the fuses from backside of instrument are not defect.

14.2 Valve board and valve issues

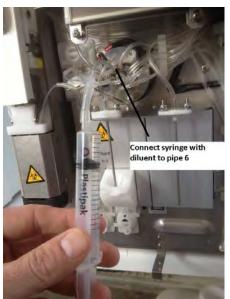
If none of the valves are working, make sure that 24V is present to the board, see section 12.1.6. If some of the valves are working and some are not, check the valves from service menu-Pump&valve. If one valve does not work properly then try to switch valve cable with next valve to make sure that problem is related to the valve it self, connector or valve board.

In case valve board is defect we can not recommend to repair valve board easily as the layer is surface mounted and not easy to solder on. If problem persist, replace valve board.

14.3 Shear valve movement issues (Indication 71, 75)

In case indication 71 or 75 appear during power on, this can be related to that shear valve is stuck due to long term shutdown and some salt crystals inside the shear valve obstruct the movement If the shear valve will not perform the initialization: Activate Flush shear valve from Service menu a couple of times. If problem persist, connect a syringe with diluent to pipe 6 and press liquid back and forward through pipe 11, this to lubricate the shear valve inside.

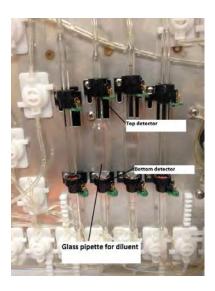
Flush syringe back and forward like 20 times and in same time press Init button several times from Service menu 2-Shear valve. Also make sure that the allen screws between motor/gearbox and shaft to shear valve is well tighten.





14.4 DP and DF error flag

DP or **DF** flag is an indication that glass pipette for diluent can not be emptied or filled properly during a sample/background cycle. Reason for this can be related to many different things. In case DP or DF flag appear, no results will be displayed on screen.



DP is an indication that diluent pipette can not be emptied below lower level detector within a certain time. To empty the pipette, instrument use pressure from an air pump P+. In case this DP flag appear, below message will be displayed.



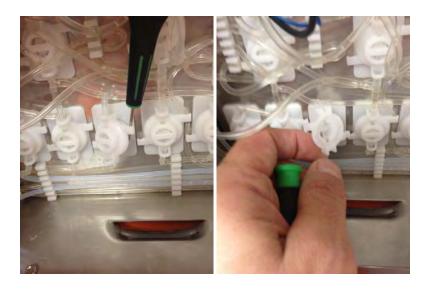
Air pump 1091268_S

Some rear cases of DP can also appear if the thinner measuring glass pipettes for RBC and WBC can not be filled properly during a prime or fill system.

Likely cause for DP flag can be related to several things:

1: Bad capacity from air pump, check air pump from Advanced-Service menu-Pump&Valve-42.Air pump. Press and hold start plate behind OT needle and pump will be activated. DC air pump should normally generate above 500mbar and AC pump (old model) should normally generate above 700 mbar. Working range down to 200-300 mbar can be accepted for both pump models. This can be checked with an external pressure meter connected direct to pump.

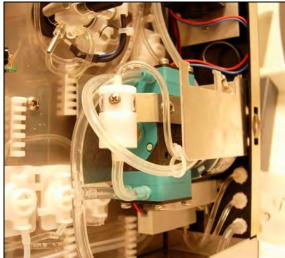
2. Check for pinched silicon tubing's inside valve 16, 17 or 18. Remove pinch valve hat and check silicon tubing inside valves. In case instrument has been shutdown incorrect for longer time then remove all pinch valve hats inside instrument and check/replace silicon tubing's. Also check that all valves respond well from Service menu-Pump&Valve test.



- 3. Shear Valve settings are not correct and cause that dilution can not pass through pipe 2-4 or 8-10 properly. Check that shear valve has same settings as yellow sticker which is present on motor/gearbox as from Service menu 2-Shear valve. In case settings are correct then check that there is no partial blockage between pipe 2-4 (Pos2) or 8-10(Pos3). Connect a syringe to pipe 2 and try to flush out of pipe 4 when Pos 2 is activated from Service menu 2-Shear valve. Connect a syringe to pipe 10 and try to flush out of pipe 8 when Pos 3 is activated.
- 4. Check that Level detector for glass pipettes (top and bottom) responds well when pipette is filled and emptied manually with a syringe. Advanced-Service menu 2-Level detector. See page 6 and 7 for this procedure
- 5. Check that washing of OT/CT needle and premix cup can be performed, if not: DP can also be generated during this cycle. For more detailed troubleshooting see our 21 pages flow diagram.

DF is an indication that diluent pipette can not be filled above top level detector within a certain time. To fill the pipette, instrument use vacuum from upper part of waste pump P-. In case DF flag appear, below message appear and no results will be displayed on screen.





1150495 S, Waste pump

Likely cause for DF flag can be related to several things:

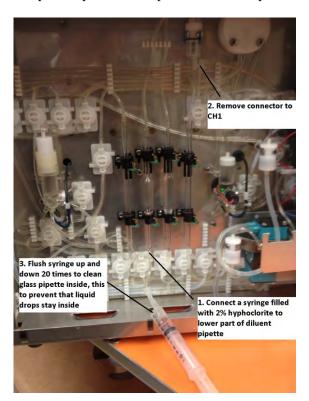
- 1. Bad capacity from waste pump could be needed to replace repair kit 1150521 after some time use. Check the waste pump from Advanced-Service menu-Pump&Valve- 0.Waste pump. Press and hold start plate behind OT needle and pump will start. Vacuum from pump should normally be around 700 mbar for both upper and lower part. Pump has a working range down to 500mbar. This can be checked with an external vacuum meter connected to the pump. Also 1504111 Boule cleaning kit procedures can increase the capacity of the waste pump.
- 2. Check for pinched silicon tubing's inside valve 16 to valve 22. Remove pinch valve hats and check silicon tubing inside valves. In case instrument has been shutdown incorrect for longer time then remove all pinch valve hats inside instrument and check/replace silicon tubing's. Also check that the valves respond well from Service menu-Pump&Valve test.
- 3. Check that Level detectors for glass pipettes (top and bottom) responds well when pipette is filled and emptied manually with a syringe. Advanced-Service menu 2- Level detectors.

See page 6 and 7 for this procedure

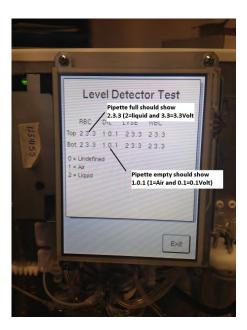
4. Sometimes DF problem can be related to that liquid drops remain close to top detector in diluent glass pipette when pipette should be empty. In this case instrument think pipette is filled but in real life it is empty and generates DF/DP. This situation can appear if glass pipette is dried out from inside and diluent can not move in and out properly, see below picture. This situation can appear in new instruments if they have been stored in box a longer time before installation



5. These liquid drops can cause false signal to top detector and cause intermittent DF/DP. To remove possible liquid drops close to top detector follow procedure below



- 1. Check that Level detector for top and bottom works properly from Service menu 2- Level detector. Connect a syringe with diluent on bottom side and move liquid in or out to make sure that detector responds well.
 - In case detector show 0=undefined with voltage like 0.8V then try to manually turn pipette by hand to understand if something else could be the problem like a faulty level detector or misaligned glass pipette.
- 2. If problem persist replace glass pipette 1100022, this in case the glass surface inside pipette is irregular and liquid remains on the surface easier.



Note!!

In case instrument generate LP or LF flag similar problems as above can appear but then related to Lyse glass pipette which is present to the right side of Diluent pipette

14.5 Aspiration failure AF flag OT and CT mode

AF flag during sample/control analyze is an indication that sample detection is not working ok or that blood can not be aspirated in to shear valve.

In case AF flag appear, usually below display picture will be shown with similar results as from a background count.

Note!! AF flag appear in case customer performs background from blood profile and this is not an instrument problem

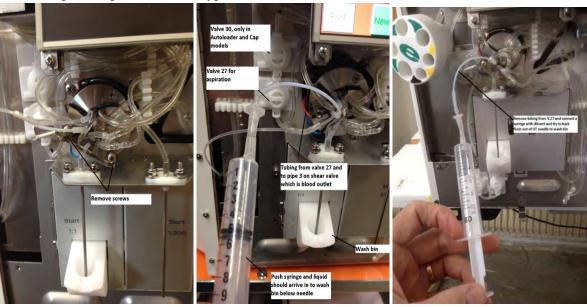


Likely cause for AF flag is probably an obstruction in aspiration line:

- 1. Loose 2 screws and remove metal tube holder on front of shear valve
- 2. Remove tubing from valve 27 and connect a syringe with diluent to start with.

 Gently push the syringe to see if liquid can move out to open tube needle and in to wash bin.

 Repeat the procedure with hypochlorite to see if the clot will be removed.

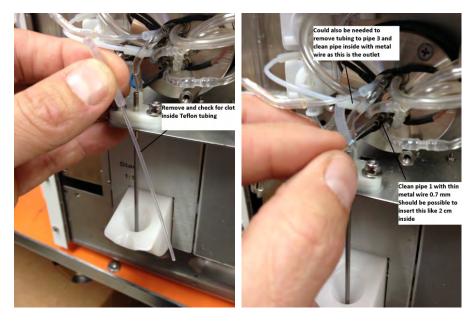


BM800 Human CT model

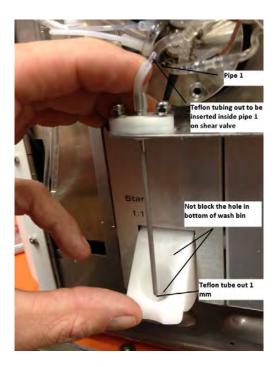
BM800 VET model

Section 14 Version 02

3. If the clot is still present somewhere, remove Teflon aspiration tubing as below and clean shear valve and aspiration tubing.



When Teflon aspiration tubing should be mounted back, pay attention to that hard Teflon tubing should be inserted inside pipe 1 and then soft tubing out side metal pipe to fix hard tubing. Also a small piece of Teflon material should be visible in the end of the OT needle. Length for this aspiration Teflon tubing is normally 14 cm

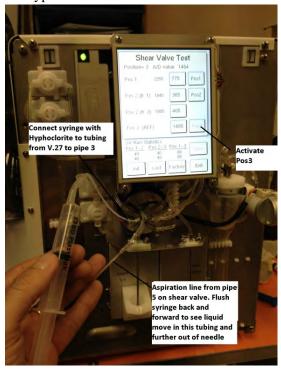


- 4. AF flag can also be related to that Shear valve is not correct aligned for Pos 1, check that shear valve settings from yellow sticker which is mounted on motor/gearbox correspond with settings from Advanced-Service menu 2-Shear valve. Check that you easily can push liquid through pipe 3 and pipe 1, further out of Open tube and in to wash bin.
- 5. In case AF flag appear and instrument aspirate a lot of samples but results seems ok, then problem is probably related to dirty conductive blood sensor between pipe 3 and pipe 1 inside shear valve. Connect a syringe as above and clean aspiration path with 2% Hypochlorite for 5-10 min. Also check that blood detector responds well from Service menu 2-Blood detector.
- 6. Check that waste pump works ok, lower part of waste pump take care about the aspiration. Go to Service menu-Pump&Valve-0.Waste pump. Hold and press start plate behind OT needle to see that pump works properly. Vacuum for the lower part should be as for upper part around 700 mbar. This can be verified with an external vacuum meter. Working range can be down to 500 mbar. Normal aspiration time is usually around 0.3 to 1 sec. Incase vacuum is lower then expected from pump, then replace 1150521 Repair kit to increase the pump capacity.

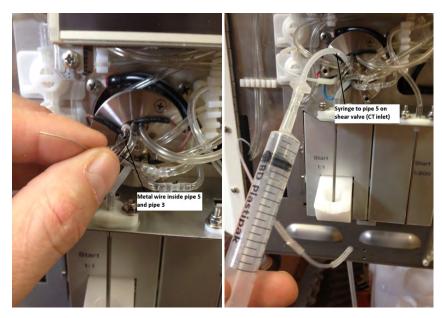
Closed tube aspiration for Cap and Autoloader

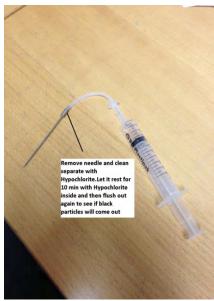
AF flag from closed tube aspiration are probably related to an obstruction in aspiration path from CT needle, aspiration tubing, between pipe 3 and pipe 5 on shear valve, valve 27 or lower part of waste pump.

Connect a Syringe with diluent to pipe 3 as below, go to Service menu 2- Shear valve and click Pos 3 button. Then pipe 3 and pipe 5 on shear valve will be connected together.
Push the syringe gently to see if liquid can move in Teflon aspiration tubing.
Repeat the procedure with Hypochlorite



- 7. In case AF flag or various result persist, then remove close tube needle and wash this separate with Hypochlorite, see section 4.
- 8. Sometimes problem could be related to a rubber piece from sample cap which is stuck in shear valve or aspiration line somewhere. Then we recommend to loose tubing's from aspiration between needle and shear valve to look for rubber part. Could also be a good idea to push a metal wire (0.7mm) inside pipe 3 and pipe 5 and then back flush with a syringe to see if some rubber comes out from shear valve. In case Teflon aspiration tubing (9970119) needs to be replaced, length for autoloader is 30 cm and for Cap 19 cm. These complete tubing's with correct length and mounted silicon pieces can be order separate. 1091192_S Sampler tubing and 1091171_S Cap needle. Also needles are available 1091437_S for autoloader/sampler and 1091352_S for Cap.





14.6 High PLT with SE or DE flag

SE flag is an indication that external/internal noise etc. are interfering during count. Usually SE flag can appear behind RBC and PLT parameter as this is most sensitive channel, smallest particles are measured in this area. If SE flag appear the problem is seldom related to particles inside instrument. If high PLT numbers followed by DE flag appear this is usually related to particles and 1504111 Boule cleaning kit procedure is recommended. Sometimes SE can also appear if counting time inside measuring pipette is very irregular of some reason. Then visual check how liquid meniscus move in measuring pipette during count.





Likely cause for SE flag:

- 1. Check Noise test from Service menu-Noise test. Should show 0 for RBC and WBC channel. In case higher signal from Noise test this will also affect the result.
- 2. Make sure instrument is properly grounded, connected to UPS or CVT, this as a bad power line in to instrument can cause electronically noise to instrument. See section 7. This interference should normally been seen from Noise test though. Make sure that all covers are mounted on instrument as light and other high frequent signal can interfere during count.
- 3. Partial defect 1141414_S, external Power converter can also cause electronically Noise
- 4. Check that RBC offset is set to 0.0mV from P30 on CPU board, see service manual 6.3.
- 5. Replace 1091325_S, RBC measuring chamber
- 6. Replace CPU board

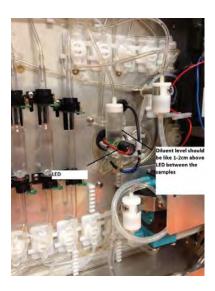
High PLT with DE flag

In case high PLT background with DE flag appear this is usually related to particles/contamination inside tubing system. In this case recommendation would be to perform 10-20 background and see if PLT value become lower and reach below 10. If problem persist then recommendation would be:

- 1. Replace diluent container
- 2. Perform a couple of Clean orifice from Maintenance menu and several backgrounds
- 3. Perform Boule cleaning kit from Maintenance menu-Cleaning menu
- 4. Replace tubing's and perform service maintenance
- 5. Replace RBC chamber

14.7 HL, HH and HF flag related to HGB

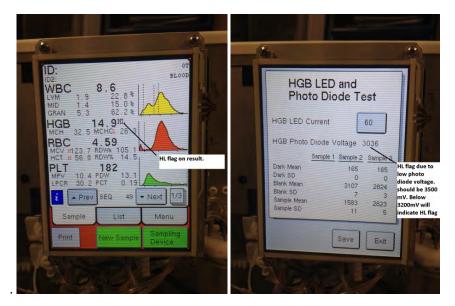
HL, HH and HF flag are an indication that photometer measurement of HGB is not 100% ok. This flag is activated in relation to the photometer voltage measured through WBC chamber with absorbance. Working range for the photometer is 3200-3800 mV with a target value on 3500mV. Between the samples it is important that the diluent level inside WBC chamber is like 1-2cm above the LED. This as the instrument measure the HGB blank on this solution. In case the diluent level is below or around the LED, the blank measurement can be to low in voltage and cause faulty HGB result.



In case diluent level is too low in WBC chamber between the samples, it can be related to that upper part of waste pump has a lower capacity < 500mbar. In this case replace 1150521 repair kit. Problem can also be related to partial pinched silicon tubing's in some of the valves which are involved in the filling process. In case instrument is placed on higher altitude, this can affect the filling of chamber between the samples. If so "High alt compensation" can be activated from Advanced-Setup menu 3-High Alt setup. Set this to 1 (Authorization code 3819-Ok-Ok) perform a background to see that diluent level will increase inside WBC chamber. Power off and on instrument and perform one more background to make sure no flags appear on screen. During "High alt compensation" some valves will be open longer time to be able to create more vacuum during filling process of chambers.

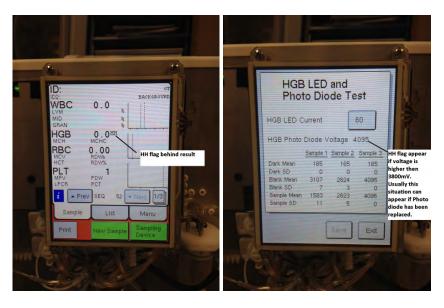
Note!! In case instrument is present at normal altitude close to sea level "High alt compensation" should not be necessary to activate but can be useful to check if flagging will disappear.

HL flag is an indication that photometer voltage is too low and out of working range. After installation photometer voltage start to decrease as the LED slowly loose intensity, this can be compensated with increase of gain (RV5) or LED current (Service menu)

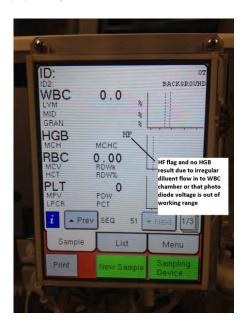


In case HL flag appear it is possible to Increase LED current 60 from Service menu 2-HGB. Click 60 and put in 63 for example and check that HGB Photo Diode Voltage increase to 3500mV, then click Save and with Authorization code 3819-Ok-Ok. Second option which we recommend to perform if someone is present on site would be to adjust gain from amplifier part on CPU board. LED current should be set to 60 and RV5 on CPU board can be increased CW and in same time check that Photo Diode Voltage increase to 3500mV, this procedure is described in service manual 6.4.2.

HH flag is an indication that photometer voltage is too high and out of working range. This situation can appear if photometer cable or WBC chamber has been replaced of some reason. In this case adjust Photometer Diode Voltage as explained above.

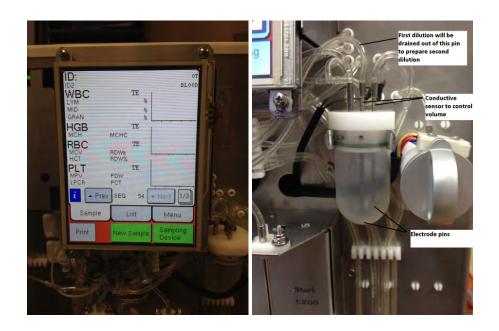


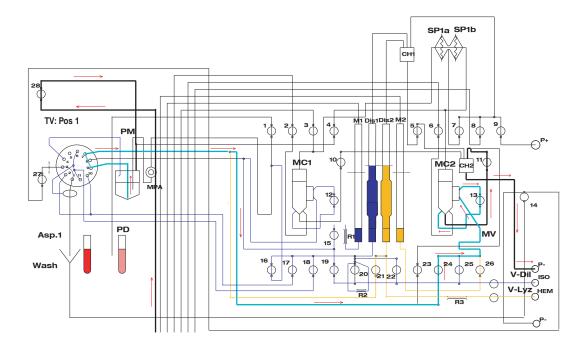
HF flag is an indication that diluent flow inside WBC chamber is irregular between the samples. Can also be that voltage from photo diode to detector various to much. This can be due to much air bubbles are generated in side chamber of some reason. Also check that photo meter cable is inserted all the way in to WBC chamber and is not loose of some reason. Sometimes vibrations during shipment can cause that photo diode is a little bit loose. In case diluent level is to low in WBC chamber, foam etc can cause that HF flag appear due to liquid level are close to LED level. If so check waste pump capacity or change High alt settings as described above. Also check that Photometer Diode voltage are set to 3500 mV from Service menu 2-HGB



14.8 TE flag

TE flag is an indication that it takes to long time to empty premix cup during preparation of second dilution. Instrument dispenses 4.5 ml diluent together with a small amount of blood in to premix cup for first dilution. Then instrument will aspirate this dilution out of premix cup further in to instrument to prepare second dilution. Instrument controls the amount of this liquid with a conductive sensor which is present between two electrode pins inside premix cup. In case the draining time during this step take more then 7 sec or less then 2 sec, TE flag will be generated. Normally this time is around 3-4 sec





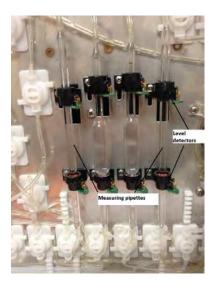
Likely cause for TE flag:

- Obstruction between pipe 7 and 9 in shear valve
 Go to Service menu 2-Shear valve and click Pos 1 (should be grey marked)
 Connect a syringe to pipe 9 and make sure you can press out liquid through pipe 7 without high obstruction,
- 2. Pinched silicon tubing's inside valve 24, 13 or 11, remove pinch valve hats and check tubing's inside these valves, follow the light blue fluidic line schematic above

- 3. Bad capacity of upper part of waste pump
- 4. Miss aligned shear valve for which cause that pipe 7 and pipe 9 are not connected properly
- 5. Faulty conductive sensor on premix cup, check functions from Service menu 2-Beaker detector
- 6. Air ventilation line to premix cup is blocked, clean metal pipe on premix cup which is connected to V.28 and further
- 7. Defect Shear valve

14.9 TU and TL flag for RBC and WBC

TU and TL flag are an indication that liquid meniscus inside measuring pipette is not moving properly or that level detector it self has a problem. Most cases of TU/TL appear due to a blockage inside orifice/aperture for WBC side, this as the highest concentration of dilution (1:400) will be present inside WBC chamber.



TL flag

During a sample cycle, liquid in measuring pipette should first move down below lower detector to be ready for counting procedure. In case liquid can not move down to lower detector TL flag will be generated.

Likely cause for TL flag:

- 1: Blockage in orifice/aperture area. Fill a cup with 2% Hypochlorite and aspirate this solution from predilute inlet by pressing start plate for 5 sec, solution will arrive 1:2 diluted in to WBC measuring chamber and solve the clot within a sample cycle normally, see picture in the end of next page.
- 2. Membrane pump which generate vacuum to move meniscus down is not good, make sure that there is not liquid in tubing from top of WBC and RBC chamber up to membrane pump
- 3. Problem with Level detector on measuring pipette, check status from Service menu 2-Level detector





New membrane pump

Old membrane pump

TU flag

During the counting cycle liquid should move from lower detector to upper detector within a certain time. In case the time is to long for the liquid to reach upper detector, TU flag will appear.

Likely cause for TU flag:

- 1. Blockage in orifice/aperture area. Fill a cup with 2% Hypochlorite and aspirate this solution from predilute inlet by pressing start plate for 5 sec, solution arrives 1:2 diluted in to WBC measuring chamber and solve the clot within a sample cycle normally.
- 2. Membrane pump which generate pressure to move the meniscus up in measuring pipette is not good, make sure that there is not liquid in tubing from top of WBC and RBC chamber up to membrane pump
- 3. Problem with Level detector on measuring pipette, check status from Service menu 2-Level detector.







Aspirate Hypoclorite through predilute

14.10 WBC, RBC and PLT DE flag

DE flag for WBC, RBC and PLT is not necessary related to an instrument problem. DE is also an information flag for pathological blood sample e.g nRBC (nucleated RBC:s) PLT clumps, air bubbles, electrical disturbances, hard lysed cells. DE flag is triggered when the size distribution of the cell pulses departs from the expected one. See user manual chapter 9

In case DE flag for PLT appear, likely cause could be:

- High PLT background which shift the PLT curve
- Blood has not react enough with EDTA in tube, (rest 15 min and mix 15 min)
- MCV gain adjustment not ok
- Defect RBC chamber/orifice

In case DE flag on RBC appear, it is most related to high background or noise

In case DE flag on WBC appear, it can be related to flagging for nucleated RBC, hard lysed RBC or PLT clumping. These situation can appear and is not necessary an instrument problem. In micro capillary mode it is more common to have DE flag. This as squeezing on the finger after the puncture will easier generate PLT clumping. See user manual chapter 5.7 for recommended procedure. In case instrument is over flagging for WBC DE flagging we recommend below suggestions.

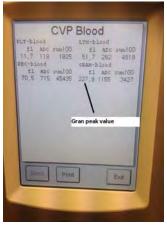
- Make sure customer use quality EDTA tubes with anticoagulant K2 or K3
- Possible to activate Less sensitive DE flag from Setup-Analyze profile-Blood-WBC setup.
- Check that WBC gain settings is correct by analyze Boule normal control, see below.

If WBC background is high with DE flag check that Waste pump is properly grounded with black cable vs back chassis of instrument. If waste pump is properly grounded perform cleaning with Boule cleaning kit

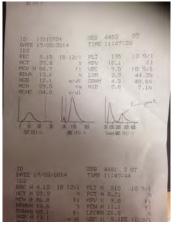
14.11 WBC gain check with Boule control

In case instrument over flag for DE on patient samples we recommend to check with Boule normal control, analyze Boule normal control from control profile, go to Service menu 2-CVP-Blood. Check Gran peak value as in below display picture. This value should be around 225 +/- 15 fl, (210fl to 240fl) for Human instruments.

Note. For Vet instruments gran peak value should be slightly higher, around 250 ± 15 fl. Over flagging for DE in VET instrument is not any problem but instrument display diff result based from WBC gran peak.



CVP from Service menu



Gran peak value from print out

In case gran peak value is complete out of range, it is possible to adjust from RV3 on CPU board. CW (increase) and CCW (decrease) gran peak value see service manual chapter 6.3. Half a lap adjustment will change like 20fl.

After adjustment a new control analyze needs to be performed and confirmed from Service menu 2-CVP-Blood for correct gran peak value.

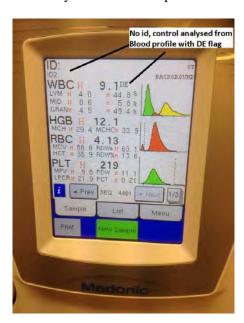
Note!! This procedure can only be done with fresh Boule normal control and no other brands of controls or patient samples, this as we know the approximately size for the populations.

A wrong adjustment can make the instrument to show incorrect WBC results.

Increase of WBC gain will increase total number of WBC and vice verse, so a calibration could be needed after adjustment.

14.12 DE flag on Boule Control

In case DE flag on Boule control appear make sure that control sample have been analyzed from correct control profile. Usually user has forgotten to barcode the control tube before analyze and control will be analyzed from Blood profile instead of control profile and DE flag is generated.





| Boule | Page 1/1 |
|--------------------------------------|-----------------------|
| Service manual BM800 Doc No 01959-01 | Section 15 Version 01 |

15. Bulletins (V01)

Bulletins are provided by Boule via the Internet support site. They are issued in case of:

- 1. Product change notification
- 2. Service/maintenance additions
- 3. Production faults/errors at certain batches/serial-numbers
- 4. Other issues that need the attention of the service staff