

# ***lagu***

## ***User & Service Manual***

**lagu Infusion Pump Tester**



P/N 15035

V. 1.49

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***Limited Warranty***

METRON warrants that the lagu Infusion Pump Tester will substantially conform to published specifications and to the documentation, provided that it is used for the purpose for which it was designed. METRON will, for a period of twelve (12) months from date of purchase, replace or repair any defective system, if the fault is due to a manufacturing defect. In no event will METRON or its local representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the lagu Infusion Pump Tester, even if advised of the possibility of such damages. METRON or its local representatives are not responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the lagu Infusion Pump Tester. Neither METRON nor its local representatives will accept, nor be bound by any other form of guarantee concerning the lagu Infusion Pump Tester other than this guarantee. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

**Caution**

The QA-IDS should be operated with de-mineralized/distilled water only. Use of other fluids such as but not limited to saline or glucose solutions may leave crystalline deposits in the pump system that may damage the unit. Use of fluids other than de-mineralized/distilled water will void the units warranty.

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# 1. Introduction

This chapter describes the Metron's lagu Infusion Pump Tester's features and specifications.

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## 1.1 lagu Features

METRON's lagu Infusion Pump Tester is a precision instrument, designed for use by trained service technicians, for testing all types of infusion pumps according to International Electro-technical Commission (IEC) Draft Standard 62.D, and IEC 601.2.24. Tests include:

- volumetric tests
- bolus tests
- occlusion alarm tests

lagu is capable of detecting a minimum volume variation of less than one microlitre in a range of 0.10 milliliter per hour (ml/hr) to 1000.0 ml/hr. Flow measurements are taken every 30 seconds, so that the measurements are independent of the infusion pump's flow rate.

Test results, shown in the lagu's LCD display, can be printed out directly, or transferred to a PC via the ansur lagu test automation software. ansur lets you design test protocols, remotely control the lagu, and store the test results.

---

## 1.2 Specifications

### 1. Flow Rate

Flow Range	0.10 ml/hr - 1000.0 ml/hr
Min. volume detection	0.18 µl
Display resolution	0.001 ml/hr

### 2. Time Interval to Achieve ± % Accuracy of Reading

**(It should be noted that the following accuracies are "theoretical" values based on the minimum volume detection and other capabilities of the unit. During the actual calibration and checkout of each lagu unit, the accuracy is verified to a 2% tolerance.)**

	1000 ml/hr	100 ml/hr	10 ml/hr
0.5%	0.6 sec	0.5% 6 sec	0.5% 52 sec
1.0%	0.3 sec	1.0% 3 sec	1.0% 26 sec
1.5%	0.2 sec	1.5% 2 sec	1.5% 18 sec

3. **Pressure Generation**

Range: - 200 to + 600 mmHg

Accuracy:

- 200 to + 200 mmHg: ± 10 mmHg

+ 201 to + 600 mmHg: ± 20 mmHg

4. **Occlusion Alarm Test**

Measurement Range: - 400 to +1500 mmHg.

Accuracy:

- 400 to + 500 mmHg: ± 10 mmHg

+ 501 to + 1500 mmHg: ± 2% of reading

Minimum Input Pressure: 2500 mmHg

5. **Bolus Test**

Accuracy: ± 20 µl

---

## 1.3 General Information

### Temperature Requirements

+15°C to +35°C when operating

1°C to +50°C in storage (do not let freeze)

### Display

Type LCD graphic display

Alphanumeric format 4 lines, 40 characters

Display control 7 function keys and a keypad

**Data Input/ Output (2)** Parallel printer port (1); Bi-directional RS - 232C (2) for Computer control

**Power** From 110 VAC to 240 VAC, 47 / 63 Hz.

### Mechanical Specifications

Housing Metal case

Height 13.5 cm / 5.31 in.

Width 23.5 cm / 9.25 in.

Depth 24.5 cm / 9.65 in.

Weight 4.30 kg / 9.48 lbs.

**Printer Port** Centronics Interface

### Standard Accessories

*lagu User and Service Manual* (P/N 15035)

### Additional Accessories

Carrying case, lagu (P/N 15100)

ansur Plug-In ,lagu (P/N 15200)

ansur Plug-In, lagu DEMO (P/N 15201)

*ansur Plug-In, lagu User Manual* (P/N 15205)

**Storage**

Store in the carrying case in dry surroundings within the temperature range specified. There are no other storage requirements.

**Periodic Inspection**

The unit should be calibrated every 12 months.



## 2. Installation

This chapter explains unpacking, receipt inspection and claims, and the general procedures for lagu setup.

---

### 2.1 Receipt, Inspection and Return

1. Inspect the outer box for damage.
2. Carefully unpack all items from the box and check to see that you have the following items:
  - lagu Infusion Pump Tester (PN 15000 or PN 15500)
  - *lagu User and Service Manual* (P/N 15035)
3. If you note physical damage, or if the unit fails to function according to specification, inform the supplier immediately. When METRON AS or the company's representative, is informed, measures will be taken to either repair the unit or dispatch a replacement. The customer will not have to wait for a claim to be investigated by the supplier. The customer should place a new purchase order to ensure delivery.
4. When returning an instrument to METRON AS, or the company representative, fill out the address label, describe what is wrong with the instrument, and provide the model and serial numbers. If possible, use the original packaging material for return shipping. Otherwise, repack the unit using:
  - a reinforced cardboard box, strong enough to carry the weight of the unit.
  - at least 5 cm of shock-absorbing material around the unit.
  - nonabrasive dust-free material for the other parts.

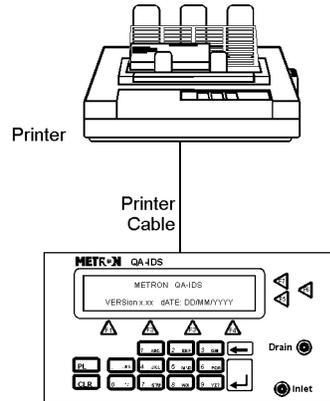
Repack the unit in a manner to ensure that it cannot shift in the box during shipment.

METRON's product warranty is on page ii of this manual. The warranty does not cover freight charges. C.O.D. will not be accepted without authorization from METRON A.S or its representative.

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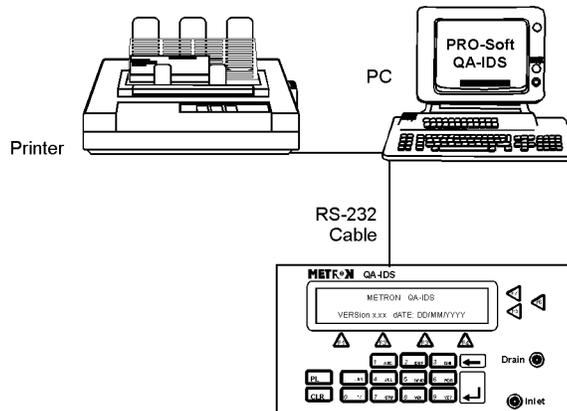
## 2.2 Setup

1. Equipment connection is as shown in the typical setup below. For direct communication to a driver free DOS compatible printer, attach the printer cable to the 25-pin outlet port on the lagu.



2. If ansur lagu is being used, attach an RS-232 (null modem/data transfer configured) cable to the 9-pin D-sub COM2 outlet port located at the rear of the lagu. Do not attach the printer cable to the lagu. *See below.* However, if you are not using ansur lagu, and are sending directly to a printer for printouts, attach the printer cable to the 25-pin outlet port.

**NOTE**  
Some RS-232C cables are missing the connection between the seventh and the eighth wires in the cable. The cable may still be called NULL-modem, but it will not work with the lagu. Refer to the ansur lagu Users Manual for more information.



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## 2.3 Power

**Main On/Off Switch.** lagu should remain off for at least 5 seconds before switching on again, in order to allow the test circuits to discharge fully.

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## 2.4 ansur lagu

ansur lagu is a front-end test automation and presentation tool for METRON's lagu Infusion Pump Tester. It allows you to conduct the same tests, but by remote control via an IBM-compatible PC/XT with MS Windows (Version 98 or later).

Each of the lagu tests can be run independently from ansur in the "Manual" test mode. Results are shown on the PC screen during testing, and the user is prompted to set the tested equipment accordingly. At the conclusion of tests, the user may print a report, store the test, and results on disk, or both. Combinations of tests can be created and stored as "Test Sequences." The program maintains a library of these sequences. In this way you can store and retrieve sequences that are appropriate for each infusion device being tested at your facility.

**NOTE**

ansur lagu has its own user manual, which contains all the information concerning the program. If you order a demonstration version of the program you also receive the manual.

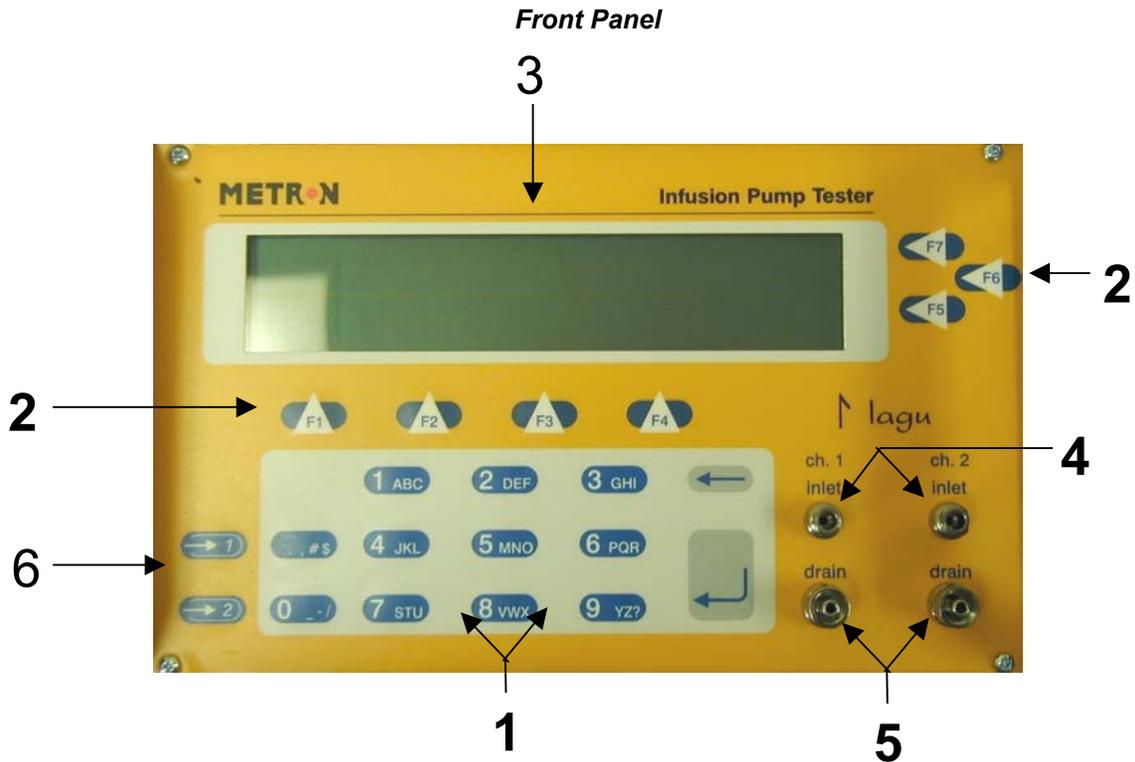
Sequences can then be used independently, or can be attached to a checklist, written procedure, and equipment data in the form of a test "Protocol." The equipment data can be entered manually into the protocol, or it may be retrieved by ansur from a database program or other equipment files. Protocols can be created easily for each infusion pump in your inventory, and stored for use. Test protocols with results can be printed, or stored on disk, and the results of testing can be sent back to the equipment database to close a work order and update the service history.

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## 3. Operating lagu

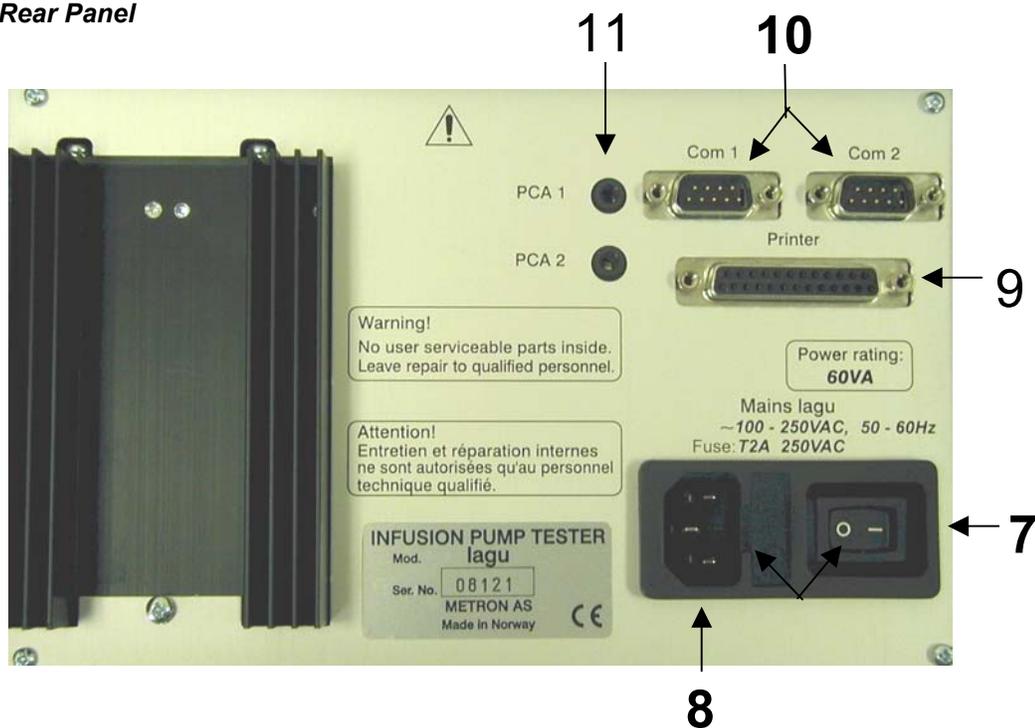
This chapter explains the operating controls, switches and menus of the lagu, details how to use them in testing, and provides instructions for printing reports, and operator maintenance.

### 3.1 Control Switches and Connections



- |                               |  |
|-------------------------------|--|
| <b>1. Key Pad</b>             | 11 alphanumeric keys, used to enter information.   |
| <b>2. Function Keys</b>       | F1-F4 are used to select the functions shown in the menu bar at the bottom of the display, i.e., for selecting the function that is directly above the key. F5-F7 are used to select the function, or enter information in the message field in the same line. |
| <b>3. LCD Display</b>         | Shows messages, test results and function menus.   |
| <b>4. Inlet</b>               | Inlet connection for infusion set.   |
| <b>5. Drain</b>               | Connection for drainage tube.  |
| <b>6. Pump Selection Keys</b> | Special function keys for selecting active pump. (No function on single channel units)   |

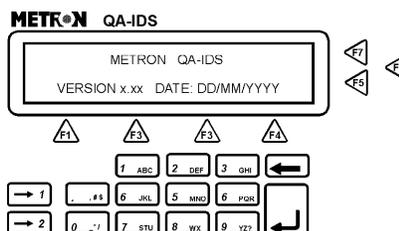
## Rear Panel



- |                                |                                       |
|--------------------------------|---------------------------------------|
| 7. <b>Power Switch</b>         | Turns power ON and OFF.               |
| 8. <b>Mains lagu</b>           | Mains connection for test instrument. |
| 9. <b>Printer Outlet Port</b>  | 25 pin D-sub. Centronic output.       |
| 10. <b>RS-232 Serial Ports</b> | 9-pin D-sub                           |
| 11. <b>PCA Connectors</b>      | Interface for PCA pump trigger        |

## 3.2 lagu's Controls

lagu's display, alphanumeric data entry keys, control keys and programmable function keys (*see below*) provide flexibility and control in testing.



lagu’s display has four lines in each screen. The top three lines are used for entry of testing parameters by the operator and for messages, and test status and results by the lagu. These are controlled by the F5, F6 and F7 keys, located to the right of the display. These keys are operational only when you see the leading arrows (“ . . .>”) pointing to the keys.

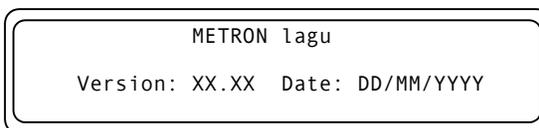
The bottom line is a menu bar, controlled by function keys F1 through F4 directly below the display. It is used for system functions, such as **PRINT**, and for inter-screen navigation, such as **MORE** and **GO BACK**.

Pressing and holding down one of the 11 alphanumeric keys causes it to move automatically from character to character. For example, pressing the “1 ABC” key and holding it down will scroll you automatically through “1”, then “A”, “B” and “C”. Release the key when the desired alphanumeric character appears. To delete a letter or number previously entered, use the **Delete** key.

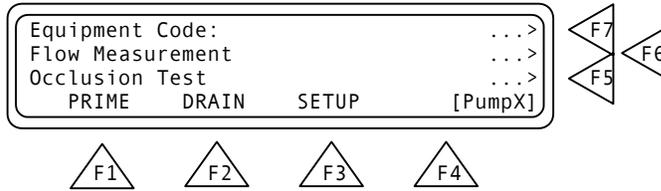
When all data has been entered on a particular line, press the **Enter** key to exit the line. When this is done the data on the line is retained until changed or the device is turned off. To avoid loss of data, store it in memory.

### 3.3 Display Menus and Messages

1. **Startup Screen.** The following screens will be displayed in sequence for the first two seconds after the lagu has been switched ON.

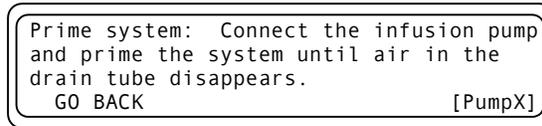


## 2. Main Menu



This window offers the following functions:

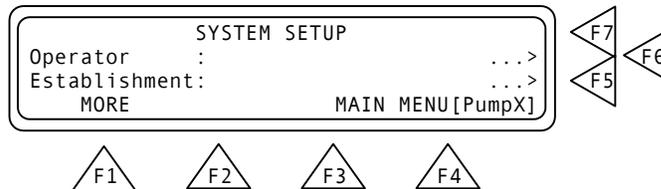
- Press **Occlusion Test (F5)** to go to the Occlusion Test Setup Screen. *See paragraph 3.4.5 below.*
  - Press **Flow Measurement (F6)** to go to the Flow Measurement Test Setup Screen. *See paragraph 3.4.6 below.*
  - Press **Equipment Code (F7)** to record the code or name of the device under test. Press **Enter** (↵) to store.
3. **PRIME (F1)**. When **PRIME (F1)** is pressed, the following display will appear:



- Press **GO BACK (F2)** to return to the main menu.

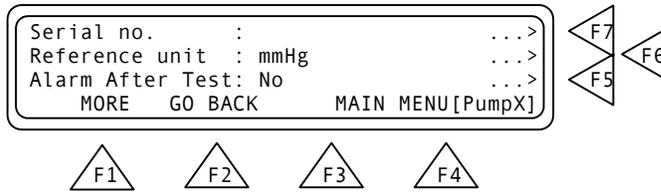
## 4. SETUP (F3)

This function is used for entering general information in connection with the test. Three main displays are shown below.



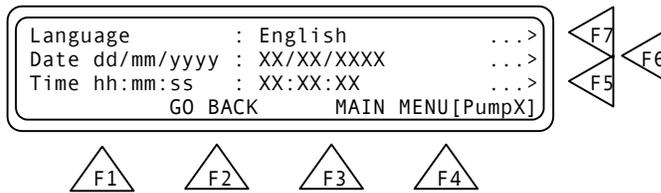
- Press **Operator (F6)** to record the operator's name or initials.
- Press **Establishment (F5)** to record the establishment.
- Press **MAIN MENU (F4)** to return to the main menu.

- Press **MORE (F1)** and the following display will appear:



- Press **Serial no (F7)** to record the serial number of the lagu being used.
- Press **Reference Unit (F6)** to select the reference unit, as follows:
 

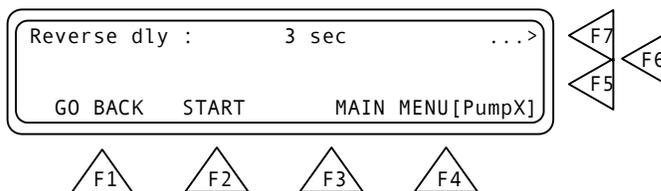
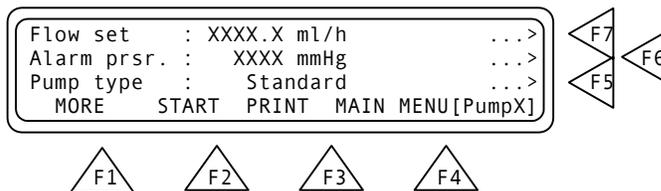
mmHg	mBar	kg/cm <sup>2</sup>	inH <sub>2</sub> O
cmH <sub>2</sub> O	kPa	inHg	PSI
- Press Alarm After Test (F5) and select Yes or No.
- Press GO BACK (F2) to return to the previous display.
- Press MAIN MENU (F4) to return to the main menu.
- Press MORE (F1) and the following display will appear:



- Press **Language (F7)** to select the language used for the testing.
- Press **Date (F6)** to set the day/month/year.
- Press **Time (F5)** to set the hour/minute/second.
- Press **GO BACK (F2)** to return to the previous display.
- Press **MAIN MENU (F4)** to return to the main menu.

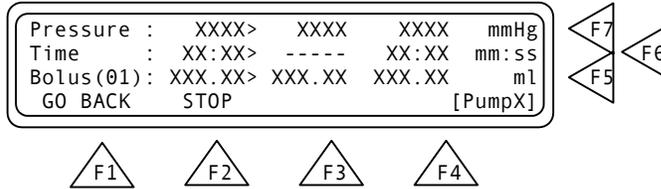
### 5. Occlusion Test (F5)

The Occlusion Alarm Test is used to protect the patient. An Occlusion Pressure Alarm will be activated if the pressure inside the administration set extends preset levels. The three main test displays are shown below.



- Press **Flow Set (F7)** to set the preset value of the infusion pump.
- Press **Alarm Prsr (F6)** to set the preset pump value.
- Press **Pump type (F5)** to select between *Standard* and *Reversing*.
- Press **MORE (F1)** to go to the next menu.
- Press **Reverse dly. (F7)** to set the delay on the reversing pump.

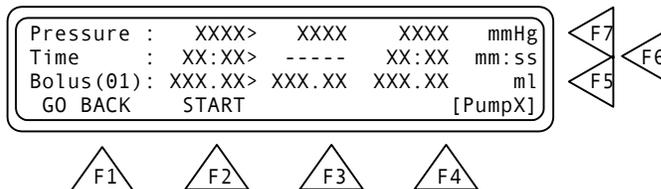
- Press **MAIN MENU (F4)** to return to the Main Menu.
- Press **START (F2)** to start the Occlusion Test, and the following display will appear:



The following parameters are displayed:

- Prsr:** The pressure in the connection tube. Measurement results display: max. value > instantaneous measured value > mean value in mmHg.
- Time:** The time from test start until alarm activation. Measurement results display: max. time > elapsed time > mean time in minutes/seconds.
- Bolus:** The volume expansion within the tube when the infusion pump alarm activates. Measurement results display: max. bolus > last executed calculation after STOP is pressed > mean bolus in milliliters.

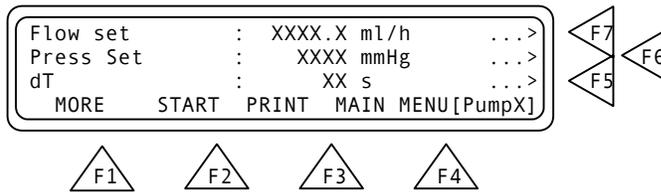
- Press **GO BACK (F4)** to return to the previous menu.
- Press **STOP (F2)** to stop the test.



- Press **START (F2)** to return to the previous menu.
- Press **GO BACK (F1)** to return to the previous display.

## 6. Flow Measurement (F6)

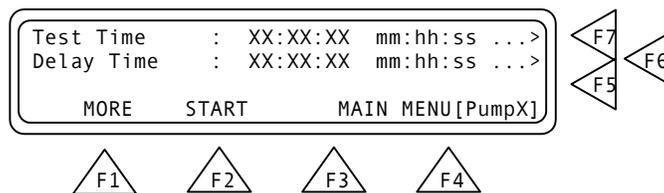
This function is used for entering flow information in connection with the test. There are four main displays, shown below:



The following parameters are displayed:

- Flow Set:** This value is the preset value of the infusion pump. All error calculations of the flow measurement are related to this value. If the Flow Set value is not entered correctly, this may cause a poor presentation with incorrect overall errors.
- Press Set:** This function enables you to enter + (positive) or - (negative) backpressure into the system. Operation range is from -200 to +600 mmHg.
- dT:** Interrogation time, or time between two measurements. Average value during the test interval is displayed. Recommended dT from IEC is 30 sec, and this is the minimum value to be selected on the lagu. Maximum dT is 600 sec. or 10 minutes. Default value is 30 sec.

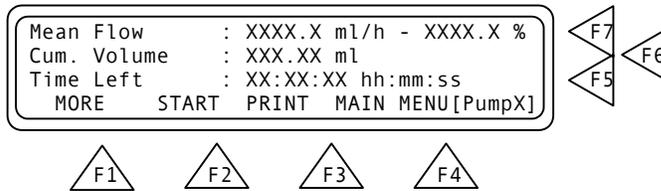
- Press **Flow Set (F7)** to set the preset value of the infusion pump.
- Press **Press Set (F6)** to set the relevant + or - backpressure into the system.
- Press **dT (F5)** to set the interrogation time, or time between two measurements.
- Press **PR HDR (F3)** to print a header.
- Press **MAIN MENU (F4)** to return to the Main Menu.
- Press **MORE (F1)** and the following screen will appear:



The following parameters are displayed:

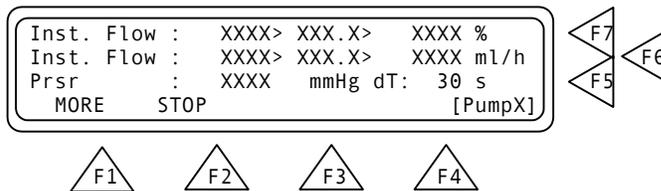
- Test Time:** This is the preset time for a test. Maximum testing time is 24 hours. Default value is 1 hour.
- Delay Time:** This is the delay before the first measuring.
- Press **Test Time (F7)** to set the actual time of the test.

- Press **Delay Time (F6)** to set the delay before the first measurement.
- Press **MORE (F1)** to return to the previous display.
- Press **MAIN MENU (F4)** to return to the Main Menu.
- Press **START (F2)** to start flow measurement, and the **Flow Measurement 1** display will appear:



The following parameters are displayed:

- Mean Flow:** The flow of the liquid volume in infusion pump every second displayed in ml/h and %.
- Cum. Volume:** The cumulative volume from start of the test.
- Time Left:** The remaining time before the test is finish.
- Press **STOP (F2)** to return to the Flow measurement setup.
- Press **MORE (F1)** and the **Flow Measurement 2** display will appear.



The following parameters are displayed:

- Inst. Flow:** Instantaneous Flow shows: max. value > mean value > minimum value in %.
- Inst. Flow:** Instantaneous Flow shows: max. value > mean value > minimum value in ml/h.
- Prsr:** The pressure in the connection tube.
- Press **STOP (F2)** to return to the previous display.
- Press **MORE (F1)** to return to the Flow Measurement Setup.

### 3.4 Printing Test Reports

Hard copy printouts of test results can be made if a printer is connected to the lagu. *See paragraph 2.2 for connecting the printer.*

To obtain a printout of the test, select **PRINT (F3)** at the completion of the test. As can be seen by the following examples, the printouts contain:

- lagu unit, operator and establishment identification.
- Tested equipment identification
- Test setup data, and detailed results.
- Test summary
- Comments

#### 1. Example Printout of a Flow Measurement Test.

```

METRON QA-IDS Infusion pump tester Ver. xx.xx
QA-IDS Ser. No      :
Operator            : E.F.
Establishment       : METRON

      - - EQUIPMENT INFORMATION - -
Equipment Code     : .....
Serial No.         : .....
Status             : .....
Group              : .....
Manufacturer       : .....
Type               : .....
Model              : .....
Location           : .....

      - - SETUP DATA FLOW MEASUREMENT - -
Flow set          : 10.0 ml/h      Test Time : 300 s
Press set         : 0 mmHg         Delay Time : 0 s
dT                : 30 s

dT   Pressure   Cum.Volume   Inst. Flow   Mean Flow
No   (mmHg)     (ml)           (ml/h)       (%)          (ml/h)       (%)
-----
1    1.57       0.08           9.25         -7.47        9.25         -7.47
2    -1.57      0.17           10.95        9.47         10.10        1.00
3    1.57       0.25           9.51         -4.87        9.90         -0.96
4    -0.52      0.33           10.03        0.35         9.94         -0.63
5    3.13       0.41           10.03        0.35         9.96         -0.44
6    -7.83      0.52           12.51        25.11        10.38        3.82
7    8.35       0.62           12.38        23.80        10.67        6.68
8    0.52       0.69           8.34         -16.60       10.38        3.77
9    0.00       0.78           10.56        5.56         10.40        3.97
10   -1.04      0.87           10.69        6.86         10.43        4.26

TEST SUMMARY:
Mean Flow          : 10.4 ml/h
Max. Peak Flow    : 12.5 ml/h
Min. Peak Flow    : 8.3 ml/h
Cum. Volum        : 0.9 ml
Measurement time   : 300 s

Comments           : .....
Date Time Signature : xx/xx/xxxx xx:xx
  
```

## 2. Example Printout of an Occlusion Test.

```

METRON QA-IDS Infusion pump tester Ver. xx.xx
QA-IDS Ser. No :
Operator       : E.F.
Establishment  : METRON

      -- EQUIPMENT INFORMATION --
Equipment Code :.....
Serial No.     :.....
Status        :.....
Group         :.....
Manufacturer   :.....
Type          :.....
Model         :.....
Location      :.....

      -- SETUP DATA OCCLUSION TEST --
Flow set      : 100.0 ml/h
Alarm Pressure : 0 mmHg

Occlusion      Alarm Time      Bolus      Alarm Pressure
Test No.      (MM:SS)           (ml)       (mmHg)
-----
1             81             1.81       1244
2             76             1.88       1251
3             86             1.78       1217

TEST SUMMARY:
Nos. of occlusion tests : 3
Mean Alarm Time       : 81 (MM:SS)
Mean Bolus            : 1.82 (ml)
Mean Alarm Pressure   : 1237.40 (mmHg)

Comments          : .....
Date Time Signature : xx/xx/xxxx xx:xx
  
```

The tested equipment and comments portions enable the operator to manually enter appropriate remarks.

## 3. Presentation of Measuring Data

- Instant Flow:** Flow rate measured during the last interrogation.
- Maximum Flow:** Max. flow detected during one interrogation period.
- Minimum Flow:** Min. flow detected during one interrogation period.
- Mean flow:** Mean flow from start of test till elapsed time.
- Cumulative Volume:** Accumulated or delivered volume during the test.
- Measured Pressure:** Measured pressure in the flowline.
- Elapsed Time:** Elapsed time from start of test.
- Time Left:** Time left of a preprogrammed test sequence.
- Delay Time:** Delay for calculation of measuring values for a test.

## 4. Scaling Conversion from mmHg to Selected Pressure Unit

mmHg	= 1	kg/cm2	= 0.0013
cmH2O	= 1.3	inHg	= 0.03937
mBar	= 0.013	inH2O	= 0.5118
kPa	= 0.13	PSI	= 0.01885

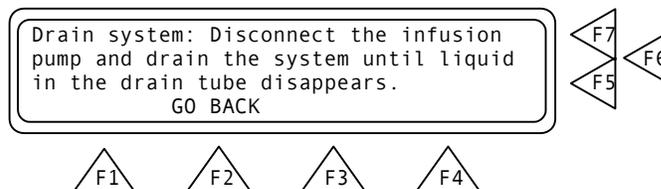
### 3.5 Operator Maintenance

1. **Draining the lagu.** To ensure proper functioning, and reduce the chance of malfunction, the lagu should be drained:

- Daily after use.
- Prior to storage.
- Prior to being transported.

To drain the lagu:

- Disconnect the infusion set from the Inlet.
- Press **DRAIN (F2)** in the **Main Menu**. The following display will appear:



- Drain the unit until the liquid in the drain tube disappears.
  - Press GO BACK (F2) to return to the main menu.
2. **Cleaning.** The lagu should be cleaned every six months, in accordance with the following procedure:

Use any of the following cleaning materials:

- Sodium hypochloride, 4% solution in distilled water.
- Acetic Acid, 4% solution in distilled water.
- Bicarbonate of Soda, 4% solution in distilled water.

Mix the cleaning fluid in distilled water.

Prime the lagu with the mixture (*See paragraph 3.4.3*).

- Allow the mixture to remain in the system for 30 minutes.
- Drain the unit, as above
- Repeat this procedure two to three times.
- Set the lagu on a one-hour flow test, with a flow rate of 100 ml/hr, using distilled water.

## 4. Infusion Pump Testing

This chapter details procedures for conducting each of the lagu tests.

---

### 4.1 Introduction

Infusion pump testers calculate flow rates from a measured time period to fill a defined volume. If it takes one hour to fill a defined volume of 10 milliliters, the flow rate is calculated to be 10 ml/hr. This flow rate is called the *instant flow rate*. The *minimum volume detection* of this measurement is 10 milliliters, since it needs that amount to calculate a flow rate. The next instant flow rate calculation may be done when an additional volume of 10 ml is delivered to the measuring device. When two or more instant flow rates have been obtained, the calculation of a *mean flow rate* can be done by averaging the instant flow rates.

Detecting unexpected flow changes requires detection of tiny infusion volumes, as flow measurements may only be calculated every time the defined volume is filled up. The ability to detect small infusion volume requires that measurements be made frequently, hence a high flow-sampling rate. The ability to detect only larger infusion volumes decreases the sampling rate, as well as the ability to accurately detect flow changes. International standards prescribe flow sampling to be done every thirty seconds for all flow rates to ensure a steady rate of infusion from all types of infusion devices. To fulfill this requirement, minimum volume detection of the measuring device is critical.

#### Example:

To test an infusion pump for unexpected flow changes at a flow rate of 10 ml/hr, with an accuracy of  $\pm 2\%$ , the following minimum flow detection is needed:

Expected flow:            10 ml/hr = 166.7  $\mu$ l pr. minute (divide by 60) = 83.3  $\mu$ l pr. 30 sec. (divide by 2).

2% of expected flow:    83.3  $\mu$ l pr. 30 sec. x 2% = 1.67  $\mu$ l pr. 30 sec.

A volume detection of 1.67  $\mu$ l is required to detect a 2% unexpected, sudden flow change from an expected flow rate of 10 ml/hr within 30 seconds.

The minimum volume detection of lagu is 0.18  $\mu$ l. That means that less than 1  $\mu$ l is needed for lagu to detect any sudden flow change between 0.10 ml/hr and 1000.0 ml/hr. lagu performs flow-samplings every second for all flow rates.

## 4.2 Test Preparation

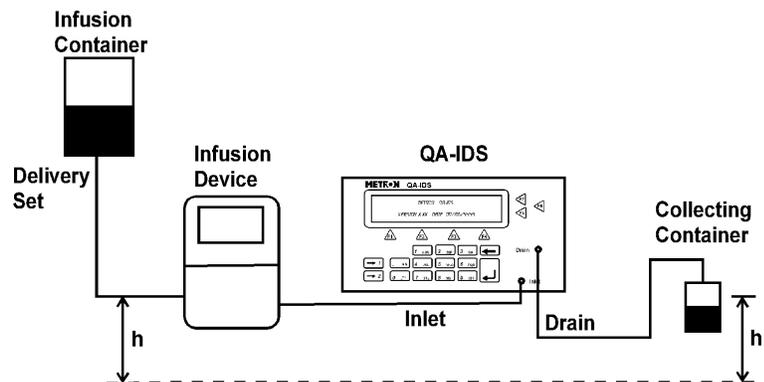
### WARNING

Do not start measuring with the lagu without having liquid in the system, as damage to the pump motor may result.

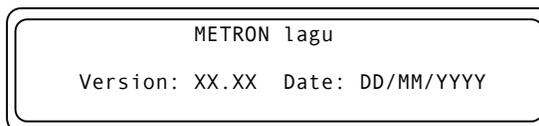
### IMPORTANT

1. Connect a drain tube with a minimum length of 10 centimeters (3.95 inches). **Do not use lagu without a drain tube.**
2. Place the collecting vessel at the same level as the lagu.
3. METRON recommends sterile, distilled water in test use, as tap water contains too much oxygen, and potentially destructive deposits.
4. Remove all air inside the administration set before connecting it to the lagu. Air passing through the measuring system will give incorrect readings.
5. Do not re-circulate the water.

1. **Set up the test components.** See below.



- Connect the infusion pump being tested to the lagu Inlet Port and to an infusion container.
- Switch the lagu **ON**. The following will be displayed in the LCD display for about two seconds:



- Fill the administration set with liquid (Metron recommends distilled water).

The placement of the collection vessel for the infusion liquid is important. According to the IEC **the output level of the administration set should be at the same level as the input level to the infusion pump during measurements**. If not, a positive or negative backpressure will be introduced in the flow line, depending on whether the output is at a higher or lower level than the input. If the difference of the two levels is large, this may have some influence on the measuring results.

2. **Prime the lagu.** Before starting the measurements, the internal volume of the lagu has to be filled with liquid.
  - Connect the administration set to the inlet of the lagu.
  - Press **PRIME (F1)** in the Main menu and the following display will appear.

Prime system: Connect the infusion pump and prime the system until air in the drain tube disappears.  
GO BACK

- Start the infusion pump with a flow rate of up to 250 ml/h. Keep the lagu working until there is no more air in the tubes. Timeout is max. 10 minutes.
- Press **GO BACK (F1)** to return to the main menu.

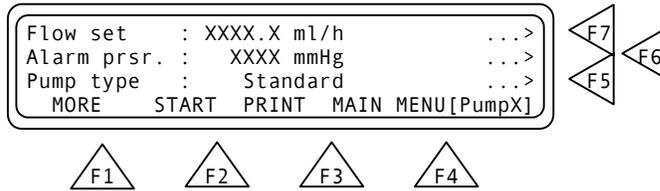
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### 4.3 Occlusion Pressure/ Bolus Volume Testing

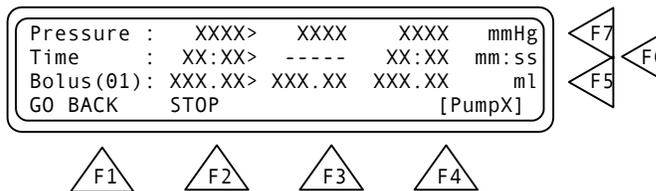
**CAUTION**  
Prime the unit properly. Do not exceed the recommended maximum priming rate of 250 ml/hr.

To protect the patient, an infusion device should include an occlusion pressure alarm. This alarm should activate if the pressure inside the administration set exceeds preset levels. Since an occlusion with built up pressure also distends the administration line, an excess volume of liquid is stored in the line. This is the *Bolus volume*, which is a discrete quantity of liquid delivered in a short time, and is not intended to form a part of the continuous flow output. Such uncontrolled volume may also be a risk to the patient, and must be measured for the infusion pump.

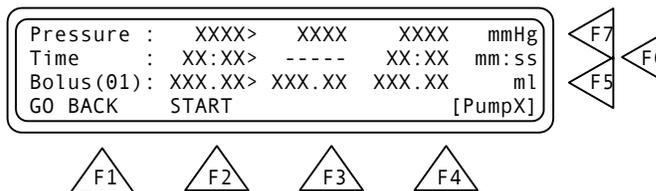
1. Prime the lagu as per paragraph 4.2.2 above.
2. Press **Occlusion Test (F5)** in the Main Menu and the following display will appear:



3. Press **Flow Set (F7)** to select an intermediate flow rate on the infusion device.
4. Press **Alarm Prsr (F6)** to enter a preset pump value on pumps having programmable occlusion alarm settings.
5. Start the infusion, and simultaneously press **START (F2)** to start the Occlusion Test, and the following display will appear.



During the test, the pressure (**Prsr**) in the administration set and elapsed time will be displayed. When the Occlusion Alarm on the infusion pump is activated, press **STOP (F2)** to stop the test, and the following display will appear.



The following parameters will then be displayed:

- Prsr:** The pressure in the connection tube. Measurement results display: max. value > instantaneous measured value > mean value in mmHg. **Note:** For multiple measurements, max. measured value > last measured value > mean value are displayed.
- Time:** The time from test start until alarm activation. Measurement results display: max. time > elapsed time > mean time in minutes/seconds.
- Bolus:** The volume expansion within the tube when the infusion pump alarm activates. Measurement results display: max. bolus > last executed calculation after STOP is pressed > mean bolus in milliliters. **Note:** Maximum

bolus volume to be measured with a standard lagu is about 1.7 milliliters.

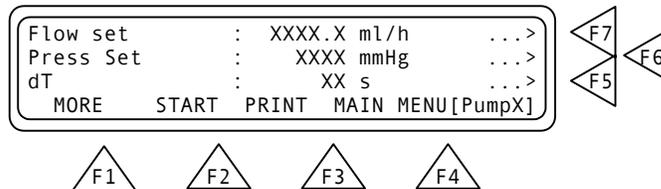
6. A new measurement in a series is initiated by just pressing **START (F2)** to start test.

According to the IEC an occlusion test should be run with different settings of flow rate and, if the pump has a programmable occlusion pressure alarm, different alarm settings are recommended.

---

#### 4.4 Infusion Flow Rate and Volume Testing

1. Press **Flow measurement (F6)** in from the Main Menu and the display will show the **Flow Measurement Setup 1** Menu.



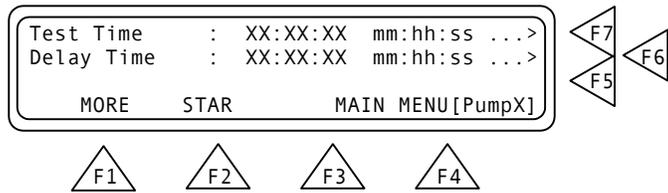
The following parameters are displayed:

**Flow Set:** This value is the preset value of the infusion pump. All error calculations of the flow measurement are related to this value. If the Flow Set value is not entered correctly, this may cause a poor presentation with incorrect overall errors.

**Press Set:** This function gives the possibility to enter + (positive) or - (negative) backpressure into the system. Operation range is from -200 to +600 mmHg.

**dT:** Interrogation time, or time between two measurements. Average value during the test interval is displayed. Recommended dT from IEC is 30 sec, and this is the minimum value to be selected on the lagu. Maximum dT is 600 sec. or 10 minutes. Default value is 30 sec.

- Press **Flow Set (F7)** and enter the preset value of the infusion pump being tested.
  - Press **Press Set (F6)** and enter in the relevant + or - backpressure.
  - Press **dT (F5)** if values other than the default 30 seconds is desired, and enter the new value.
2. Press **MORE (F1)** in **Flow Measurement Setup 1**, and the display will show the **Flow Measurement Setup 2**.

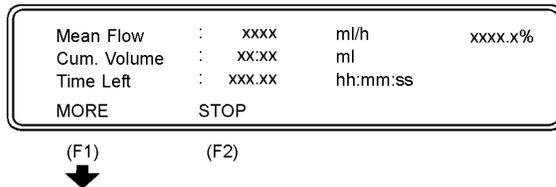


The following parameters will then be displayed:

**Test Time:** This is the preset time for a test. Maximum testing time is 24 hours. Default value is 1 hour.

**Delay Time:** This is the delay before the first measuring.

- Press **Test Time (F7)** to select a time for the test other than the default time of 1 hour.
  - Press **Delay Time (F6)** to set a delay before the first measurement, if desired.
  - Press **MORE (F1)** to return to the **Flow Measurement Setup 1** Menu.
3. Press **START (F2)** to start flow measurement in either the **Flow Measurement Setup 1** or **Flow Measurement Setup 2**, and the following display will appear:



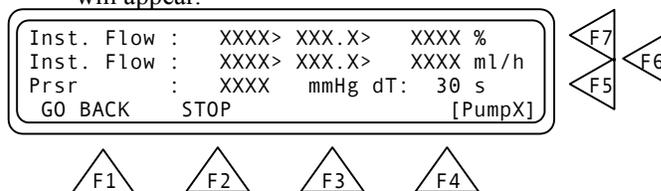
The following parameters will then be displayed:

**Mean Flow:** The flow of the liquid volume in infusion pump every second, displayed in milliliters per hour (ml/h) and percent (%).

**Cum. Volume:** The cumulative volume from start of the test.

**Time Left:** The remaining time before completion of the test.

- Press **STOP (F2)** to return to the **Flow Measurement 1** display.
- Press **MORE (F1)** and the **Flow Measurement 2** display will appear.



The following parameters will then be displayed:

**Inst. Flow:** Instantaneous Flow shows: max. value > mean value and minimum value in percent (%).

**Inst. Flow:** Instantaneous Flow shows: max. value > mean value and minimum value in milliliters per hour (ml/h).

**Prsr:** Shows pressure in the connection tube.

- Press **STOP (F2)** to return to the previous display.
- Press **MORE (F1)** to return to the **Flow Measurement Setup**.

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## 5. Control and Calibration

This chapter explains the *lagu* maintenance procedures, including factory testing and calibration. The calibration procedure for 1 and 2 pump units is identical. You just need to repeat the relevant portions for each pump your unit contains.

---

### 5.1 Required Test Equipment

- Digital multimeter, 10  $\mu$ V resolution, 0.1% accuracy.
- Pressure/vacuum generator, - 400 to + 1700 mmHg pressure.
- Pressure gauge.
- Infusion pump or flow source
- Microbalance (Test durations may need to be changed based on range, resolution, and accuracy)

---

### 5.2 Adjusting the Display Contrast



**WARNING!**  
**HIGH VOLTAGES ARE CAPABLE**  
**OF CAUSING DEATH!**

USE EXTREME CAUTION WHEN PERFORMING TESTS AND CALIBRATION. USE ONLY INSULATED TOOLS WHEN THE UNIT IS PLUGGED IN, AND THE METAL CASE HOUSING IS OFF.

1. Remove sides and top metal case housing.
2. Set contrast in the character LCD display by adjusting potentiometer R160 (located at left of CPU) to desired contrast. The contrast for the Graphical display is adjusted via software.

---

### 5.3 Upgrading Firmware

If the unit runs an earlier version of the firmware, the unit is to be updated with the latest version. The latest version can be downloaded from our website ([www.metron-biomed.com](http://www.metron-biomed.com)). It's important that the firmware is updated before continuing to the calibration procedure. The following procedure describes how to upgrade the firmware.

1. Turn on the *lagu*.
2. Press 'SETUP' (F3) from the Main Menu.
3. Press 'MORE' (F1) from the System Setup.
4. Press the Pump channel 1 button ( $\rightarrow$  1).
5. Press 'CAL' (F3).

6. Record the values for “*Prsr offset*” and “*Prsr slope*”.
7. Press ‘MORE’ (F1) and record the value for the “*pump volume*”.
8. Press ‘Main Menu’ (F4).

You are now ready to remove the old firmware and install the new one. Please note that the following steps will disable all of the functions of the *lagu* unless you finish the procedure.

9. Connect the RS-232 NULL-Modem cable between your computer’s serial port and the (COM2) port on the *lagu*.
10. Downloading the new firmware from our website will give you a self-extracting zipped file set named VX.XX.exe. Where “X.XX” is the firmware version number.
11. Run this executable file and then follow the instructions in the “FW Upload.txt” file.

---

#### 5.4 Voltage Control and Adjustment

1. Switch on the main voltage and measure the following voltages for the following test points using the DMM.

Test point → GND	Measured Value	Nominal Value	Tolerance
V24P		24 VDC	± 5%
Vcc5		+ 5 VDC	± 2%
Vcc3.3		+3.3 VDC	± 2%
V5P		5.0 VDC	± 2%
V5N		-5.0 VDC	+0.5V -1.5V
V22N		-22 VDC	±

---

#### 5.5 Pressure Calibration

1. Completely drain the *lagu* of water by using the DRAIN feature.
2. Connect an occluded piece of tubing to the outlet of the pump channel that you are testing.
3. Connect pressure generator and pressure gauge to the Inlet and start calibration of the pressure gauge.
4. Access the calibration menu.
5. Set pressure to 0 mmHg and press **F3**.
6. Set pressure to 500 mmHg and press **F4**.
7. The pressure gauge is now calibrated.

8. Turn the power off then back on after 5 sec.
9. Check that the lagu is within specifications at – 400, 0, and + 1500 mmHg pressure.

Value	Max. deviation
- 400 mmHg	± 10 mmHg
0 mmHg	± 10 mmHg
+ 1500 mmHg	± 30 mmHg

---

## 5.6 Index Calibration

To ensure an accurate regulation, perform a calibration of the index. This will cause the pump to go through 5 to 20 complete rotations to determine its index. The index value is how the *lagu* knows the beginning and end of the uptake.

1. Attach a 20cm tubs to the inlet and occlude the end.
2. Access the calibration menu.
3. Press ‘MORE’ (F1)
4. Press ‘INDEX’ (F3) to start the process.
5. Wait for completion.

---

## 5.7 Testing Flow Rate Accuracy

1. Set lagu to do a Flow Measurement, with a set flow rate (Flow Set) of 100 ml/hr, a back pressure setting (Press Set) of 0 mmHg, and a sampling interval (dT) of 30 seconds.
2. Connect infusion set of a calibrated infusion pump to the lagu inlet. **Note:** Metron recommends the use of distilled water for calibration tests.
3. Prime the lagu:
  - Turn infusion pump ON, and set flow rate at 250 ml/hr.
  - Select **PRIME (F1)** from the lagu menu.
  - Select **GO BACK** when all air is cleared from the drain line.
4. Set infusion pump to 100 ml/hr.
5. Press **START** from the lagu Flow Measurement menu.

6. Run test at each of the below settings for at least 15 minutes and check that deviations are within tolerance limits.

Flow Rate	Max. deviation	Volume	Max. deviation
+ 1 ml/Hr	± 0.05 ml/Hr	+ 1 ml	± 0.05 ml
+ 10 ml/Hr	± 0.5 ml/Hr	+ 10 ml	± 0.5 ml
+ 100 ml/Hr	± 5 ml/Hr	+ 100 ml	± 5 ml
+ 1000 ml/Hr	± 50 ml/Hr	+ 1000 ml	± 50 ml

---

## 5.8 Factory Flow System Calibration

This procedure is a gravimetric calibration and is the same procedure used in the factory to adjust the *lagu*. It is assumed that you have already performed the pressure and index calibration steps above.

### Setup:

**Temperature = 23C ±3C**

**Power on for a minimum of 20 minutes prior to testing**

**Shielded micro-balance**

**Container with a little water with some paraffin(kerosene) floating on top to greatly reduce evaporative losses.**

**Set the outlet of the flow reference and the inlet of the *lagu* to the same height.**

**Set the outlet of the drain tube going into the balance to the same height as the outlet of the *lagu*.**

1. Prime the system until there are NO air bubbles visible from the outlet.
2. Go to the flow set menu and set the flow rate to 100ml/h.
3. Set the test time to 30 minutes. (display reading 00:30:00)
4. Set the delay time to 0. (display reading 00:00:00)

5. Set your flow reference to approximately 100ml/h.
6. Start your flow reference.
7. When the flow reaches a steady state, press (START) on the *lagu* and the (ZERO) or (TARE) on the balance at the same time.
8. Stop your flow reference the moment the test period ends.
9. Record the weight on the balance and the cumulative volume on the *lagu*.
10. Using the conversion of 1g/1ml for the density of water corrected for your environment, compare the values.
11. If the values are within 2% no adjustment needs to be performed and the other flow values of 10 ml/h and 500 ml/h may be tested for 10 minute durations.
12. If the values are not within 2% the pump volume value needs to be adjusted in the calibration menu in accordance with the following equation.

$$(New\_Pump\_Volume) = \frac{(Previous\_Pump\_volume) * (Volume\_reference\_weight)}{(Cumulative\_Volume\_lagu)}$$

13. Change the pump volume to this new value and record on the measuring report.
14. Perform this procedure again starting at step 1 and use a 10 minute test time instead of 30 minutes.

The test is complete!



## **6. Component Functions and Parts**

This chapter provides a description of the functions of the lagu components, and a parts list for cross-reference.

The lagu consists of an independent primary switched power supply, a keypad board, a processor board, a LCD display and an index transmitter mounted on the pump. The processor board, keypad board and index transmitter are described in diagrams, contained in Appendix A. One is a Component Location Diagram. Another, F190.20.2000.10, is a schematic diagram describing the keyboard, pressure sensor, and pump index. F190.20.1N00.10 diagrams the Processor Board Main Part. Set F190.20. 1000.10 through F190.20.1900.10 are schematic diagrams describing the processor board by function. The boards are connected by 2 x 16-conductor flat cables, 1 x 3-conductor and 1 x 2-conductor.

---

### **6.1 Theory of Operation**

The lagu is an infusion pump tester that runs on 110 - 230 V AC mains voltage. The unit is based on a Motorola microprocessor. Controls on the front panel of the unit allow testing of all the functions of an infusion pump.

lagu performs tests according to IEC Draft Standard 62.D and IEC 601.2.24. Test results, which are shown in the lagu LCD display, may be printed out on an external printer. A serial port (RS-232C) enables the unit to be controlled from a PC, simply by using the ansur lagu software program.

The program in lagu is stored in RAM with battery backup, and can be updated from a PC via the built-in serial port.

---

### **6.2 Power Supply**

The power supply consists of a primary switched unit, mounted on the backplane, that supplies 24 VDC, 2A to the processor board (V24P). The processor board is equipped with a secondary switched regulator that generates + 5 VDC (Vcc). Via a passive filter, this is used as the supply voltage to the measurement amplifier and A/D converter (V5P). A capacitive switched supply generates - 5 VDC to the measurement amplifier and A/D converter (V5N). A reference voltage of 4.096 V is generated from V5P, which is used for the A/D and pressure sensor. The supply voltages are monitored by a watchdog, and the unit is reset if V24P falls below 20 V. The contrast on the display is regulated using R160. The stepper motor drivers are supplied directly from V24P.

---

### 6.3 Printer Output

The lagu has a printer output with a standard 25-pin D-sub contact for Centronics interface. The drivers are built up with TTL inverters, which are run from a register connected to the data bus. The inputs are protected against over-voltage.

---

### 6.4 Serial Port

The serial port has a 9-pin D-sub male (DTE), and is connected to a PC with a NULL modem cable. The handshake is carried out in the software. The control signals RTS, CTS and DTR are connected on the D-sub contact.

---

### 6.5 Microprocessor

The microprocessor unit consists of a Motorola processor with a clock frequency of 16 MHz, RAM, A/D converter, watchdog, real-time clock, parallel and serial I/O. The program is stored in a 128K RAM with battery backup. The setup parameters and calibration data are stored in EEPROM in the CPU. The LCD display and keypad are connected to the processor's bus via registers. The built-in A/D converter in the CPU is used to monitor the temperature and battery voltage.

---

### 6.6 Pressure Gauge

The pressure gauge consists of a differential pressure sensor, a measurement amplifier, the reference voltage and an instrumentation amplifier.

The pressure sensor, U1B00, is made up of a piezo-resistive element encapsulated in silicon. It is temperature- and offset-compensated. It receives its voltage supply from the reference voltage. The output signal is amplified with an instrumentation amplifier, U1B10, which is a 4 x operational amplifier. The amplified signal is proportional to the pressure measured, and is fed to a 12-bit A/D converter, U1700. To measure negative pressure, an offset of 800 mV is inserted at zero pressure. The offset is adjusted with R1 B1B. The amplification is adjusted with R1B10 to 4050 mV at 1700 mmHg. The reference voltage is generated from V5P using a variable voltage divider, R1B26, and an operational amplifier, U1B20. U1B20 is also used for temperature measurement,

---

### 6.7 Pump

The lagu has a pump from Saphierwerk, driven by a stepper motor. The pump is a rotating piston pump with the pump head and piston in artificial sapphire. It pumps 50  $\mu$ l per revolution. The pump has a circuit board with a Hall sensor to provide an index per revolution.

The index is used to measure the volume pumped. The stepper motor is a bipolar type with 200 steps per revolution.

---

## **6.8 Stepper Motor/Drivers**

The stepper motors are run by three circuits from Ericsson. The stepper motor driver U 1810 is connected to the CPU, and generates the control signal to two driver circuits. The stepper motor can run in full-and half-step mode. The driver circuits, U1820 and U 1830, have built-in temperature protection and pulse width modulation to control the current drawn. The motor drivers are supplied with 24V to achieve rapid current increase and good torque. Each phase of the motor can be supplied with up to 1.5 A, which is regulated by the software independently of the step rate. U1840 is used for synchronizing the pulse width modulation to the drivers to prevent high peak values in the current drawn.

---

## **6.9 Control Panel**

The control panel is made up of a LCD display with 4 x 40 characters and a keypad with 22 push-buttons. The function buttons control the menu choices shown on the display. The numeric and alphanumeric keys are used to enter parameters and for setups.

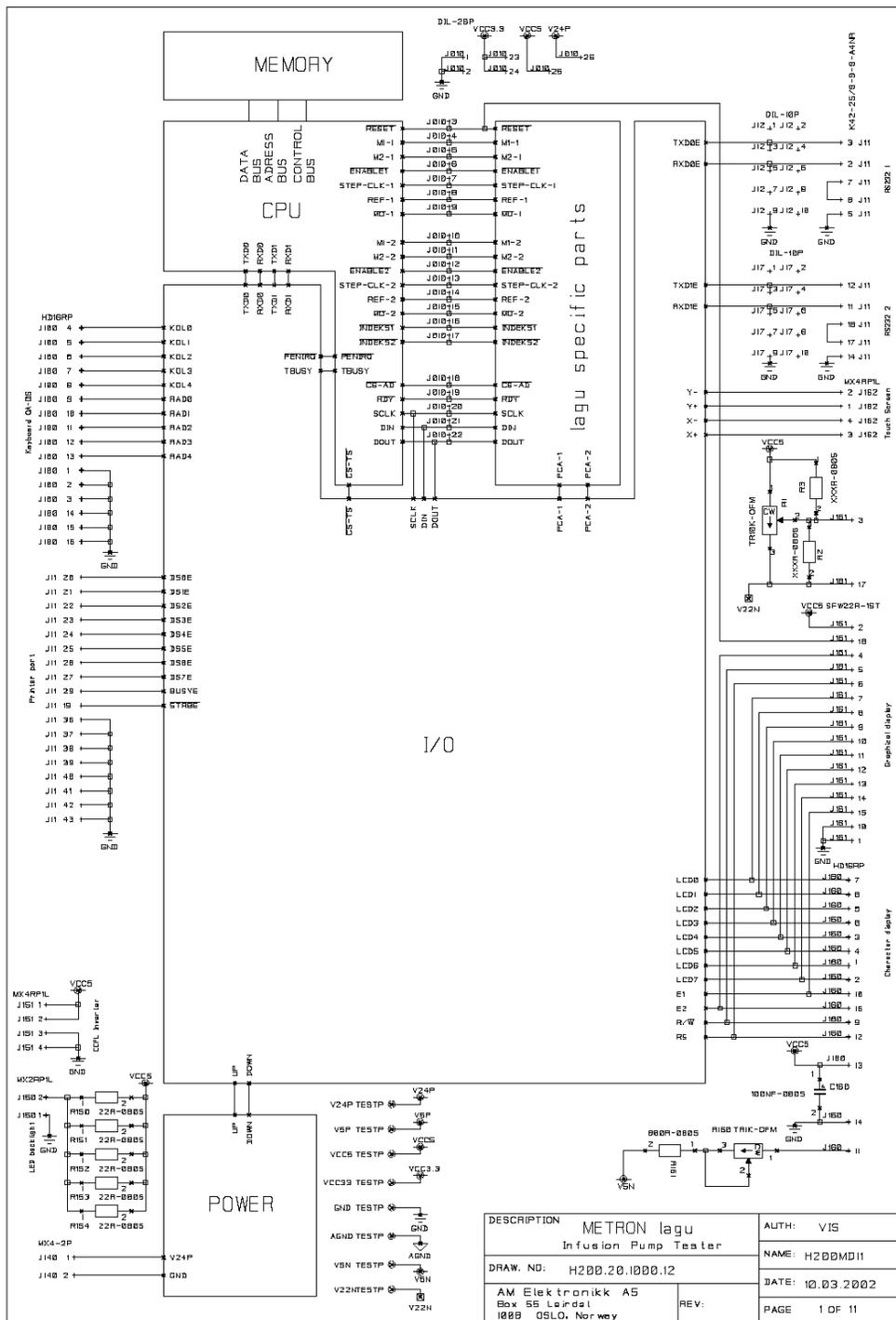
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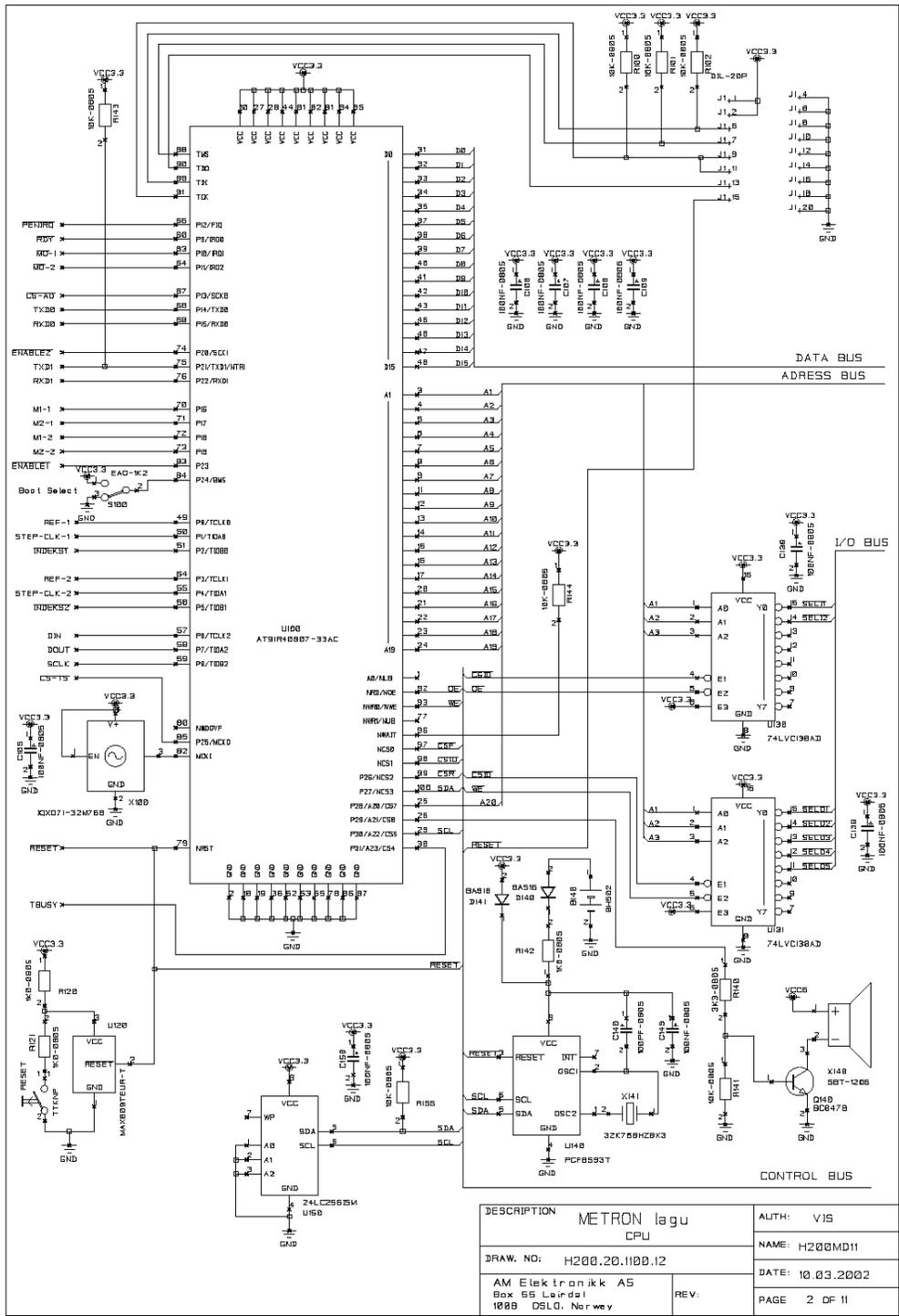
## **6.10 Component Parts**

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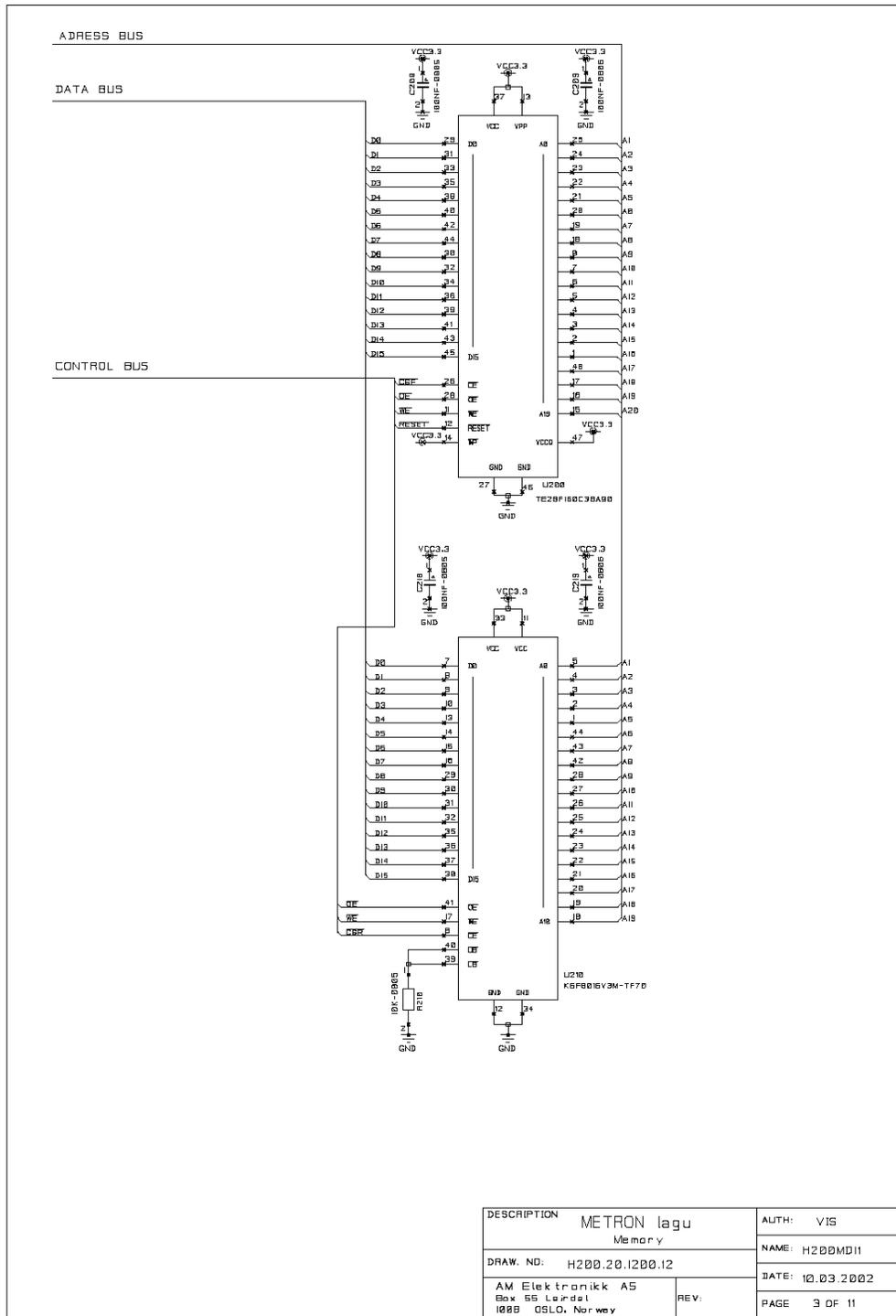
## ***Appendix A - DIAGRAMS***

Processor Board Schematic Diagram 1 (CPU) .....	A-2
Processor Board Schematic Diagram 2 .....	A-3
Processor Board Schematic Diagram 3 .....	A-4
Processor Board Schematic Diagram 4 .....	A-5
Processor Board Schematic Diagram 5 .....	A-6
Processor Board Schematic Diagram 6 .....	A-7
Processor Board Schematic Diagram 7 .....	A-8
Processor Board Schematic Diagram 8 .....	A-9
Processor Board Schematic Diagram 9 .....	A-10
Processor Board Schematic Diagram 10 .....	A-11
Processor Board Schematic Diagram 11 .....	A-12

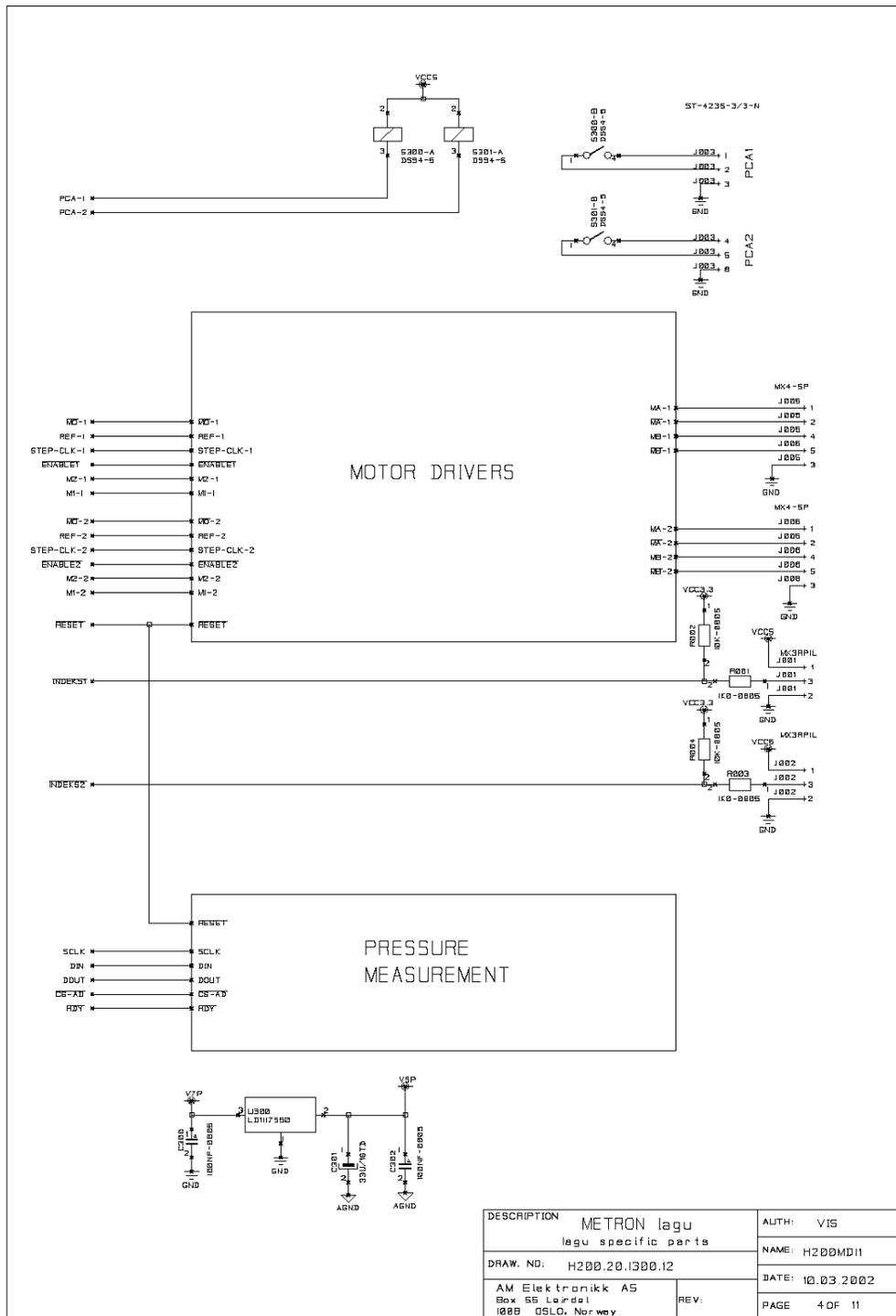




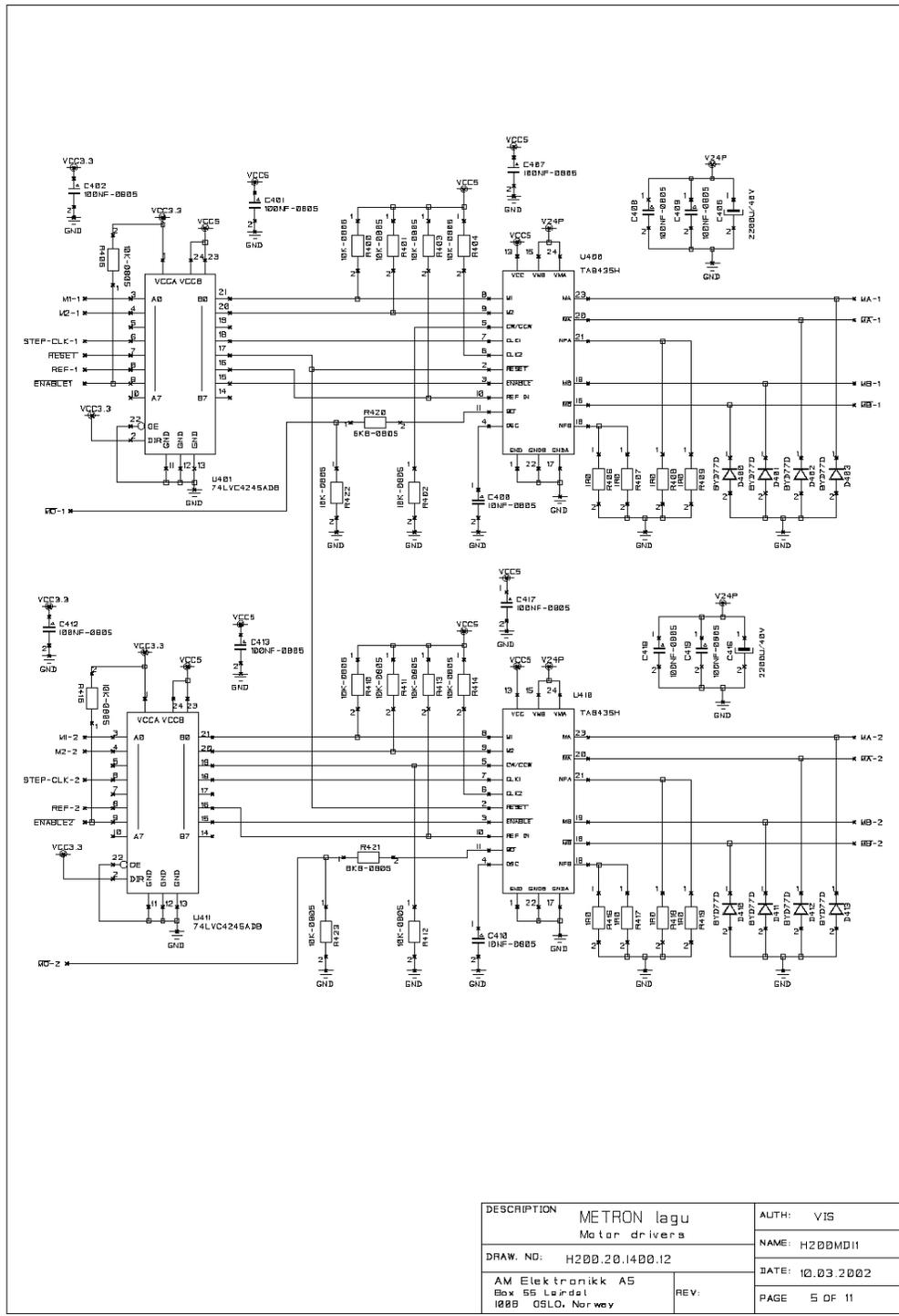
DESCRIPTION	METRON lagu CPU	AUTH:	V15
DRAW. NO:	H200.20.1100.12	NAME:	H200MD11
AM Elektronikk AS Box 55 Lindsøi 1088 OSLO, Norway	REV:	DATE:	10.03.2002
		PAGE:	2 OF 11



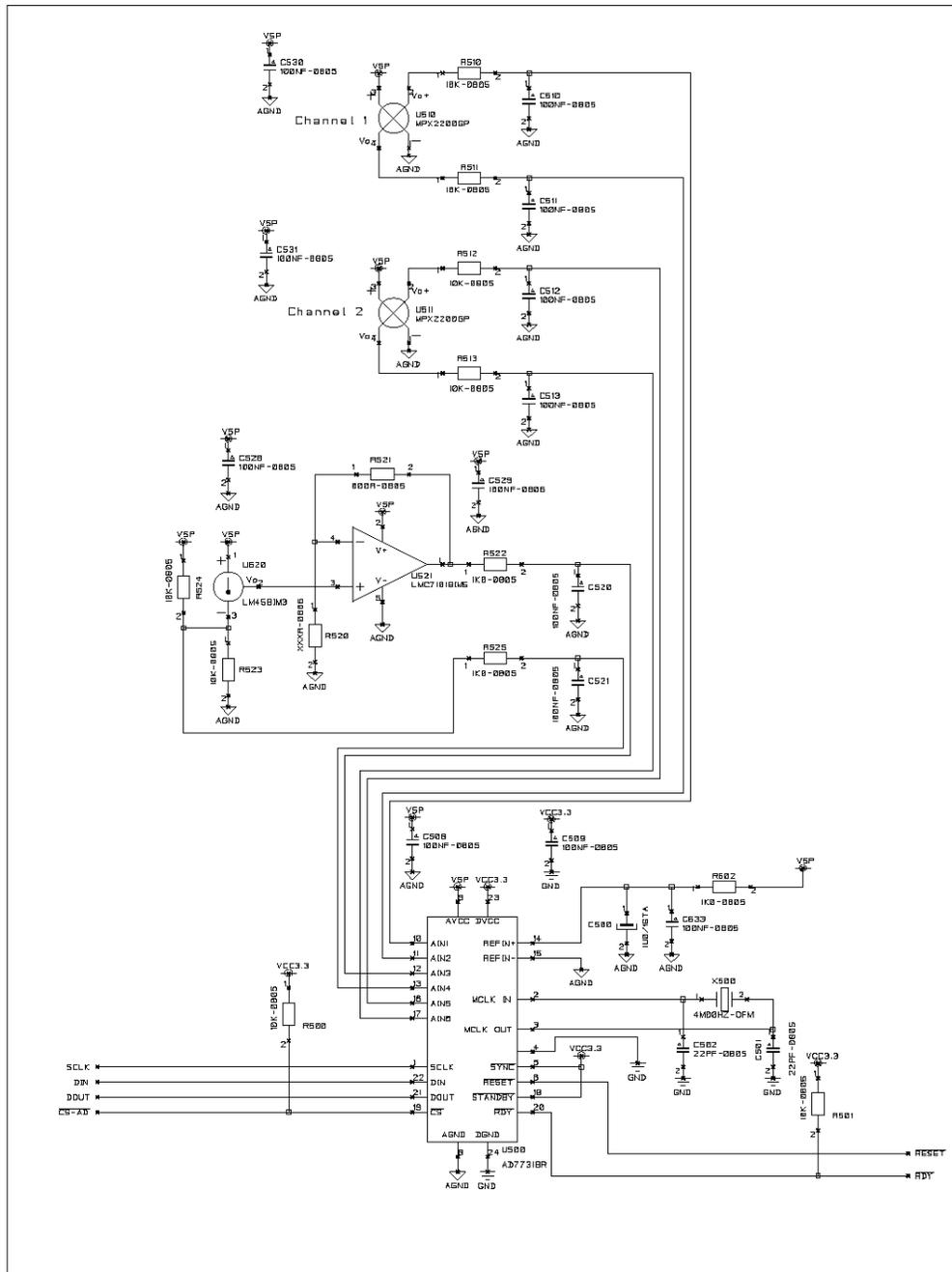
DESCRIPTION	METRON lagu Memory	AUTH:	VIS
DRAW. NO:	H200.20.1200.12	NAME:	H200MD11
AM Elektronnikk AS Box 55 Lørdst 1008 OSLO, Norway	REV:	DATE:	10.03.2002
		PAGE:	3 OF 11



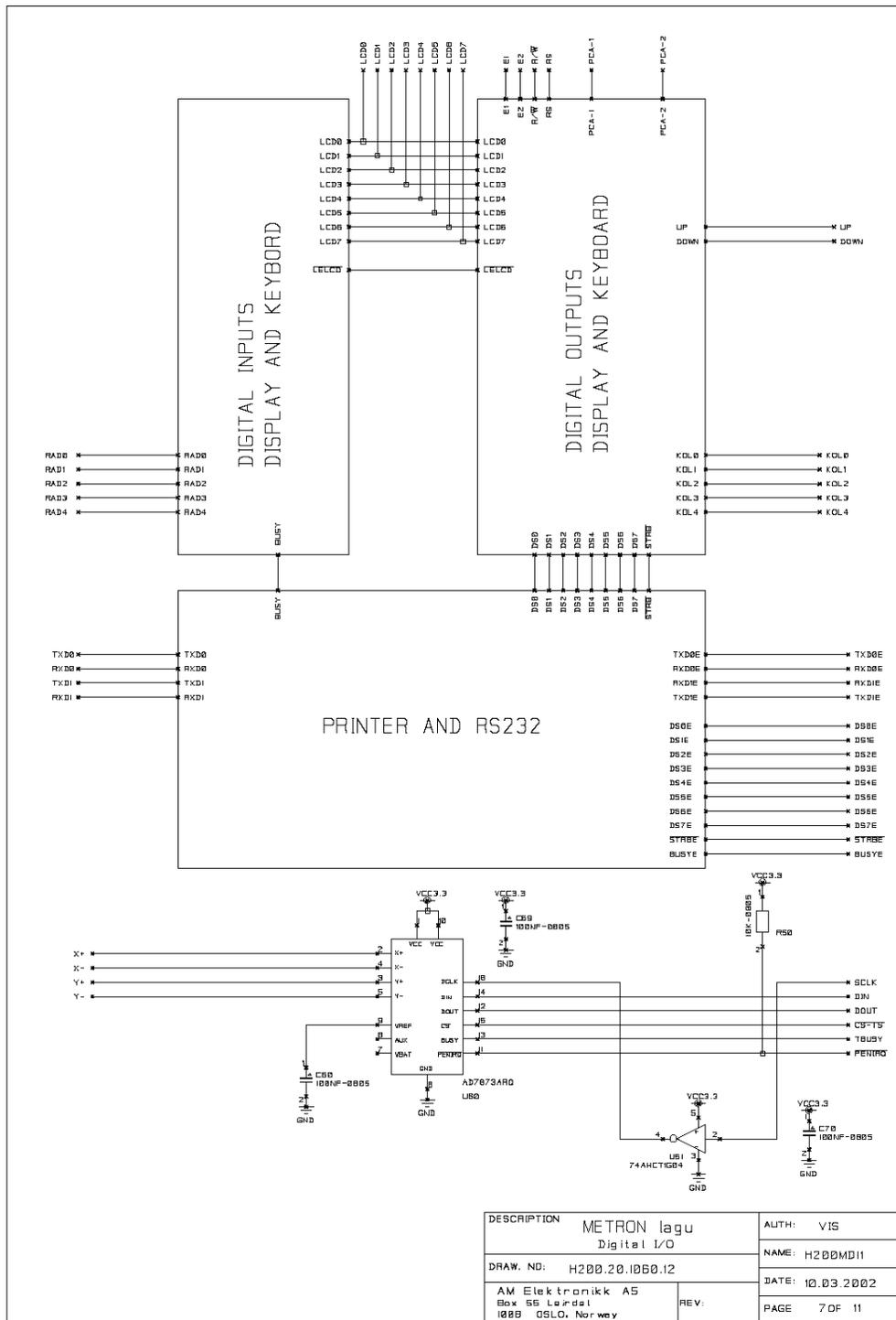
DESCRIPTION	METRON lagu lagu specific parts	AUTH: VIS
DRAW. NO:	H200.20.1300.12	NAME: H200MD11
AM Elektronikk AS Box 55 Lørdal 1080 OSLO, Norway	REV:	DATE: 10.03.2002
		PAGE 4 OF 11



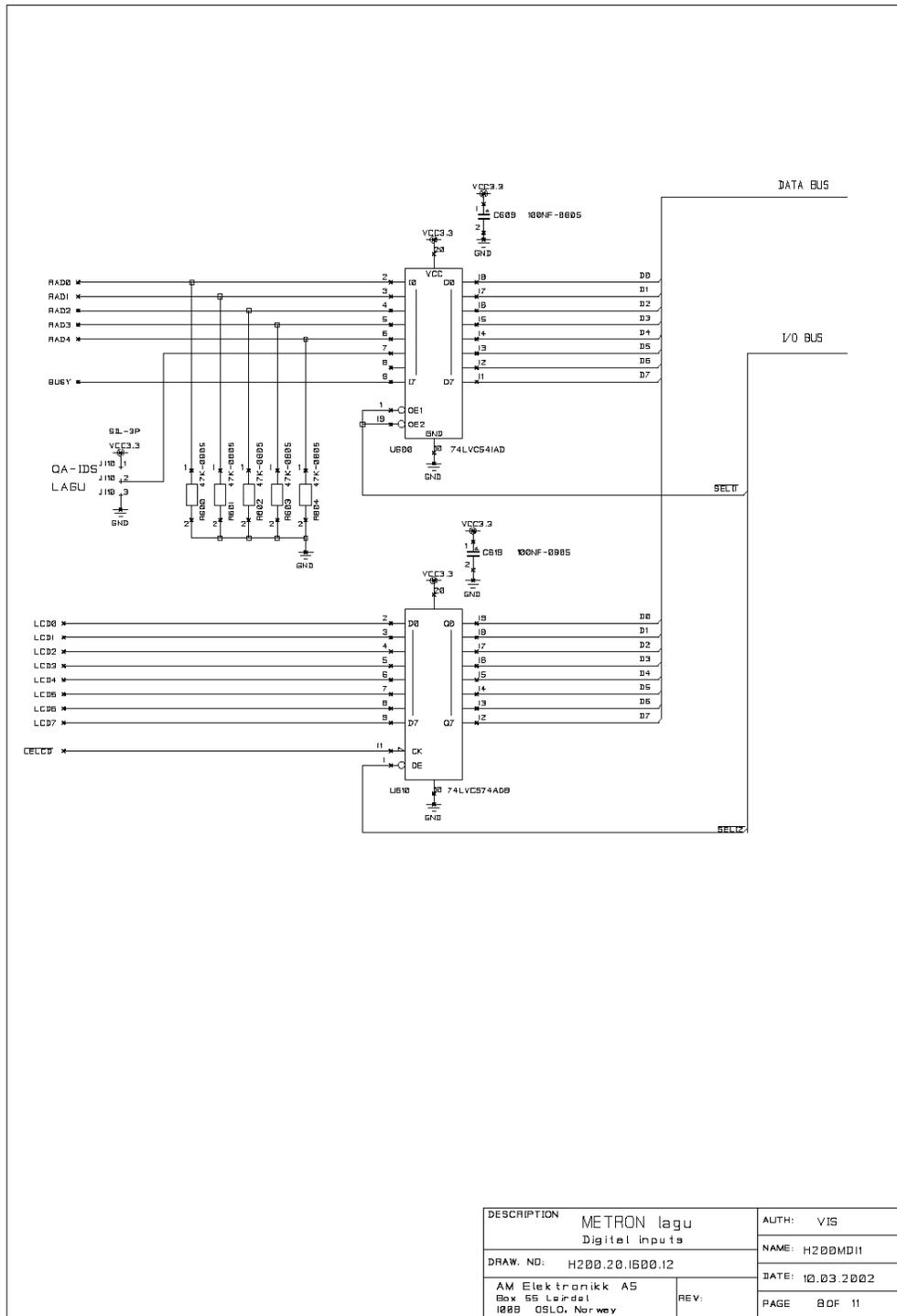
DESCRIPTION	METRON lagu Motor drivers	AUTH: VIS
DRAW. NO:	H200.20.1400.12	NAME: H200MD11
AM Elektronikk AS Box 55 Lørdal 1000 OSLO, Norway	REV:	DATE: 10.03.2002 PAGE: 5 OF 11



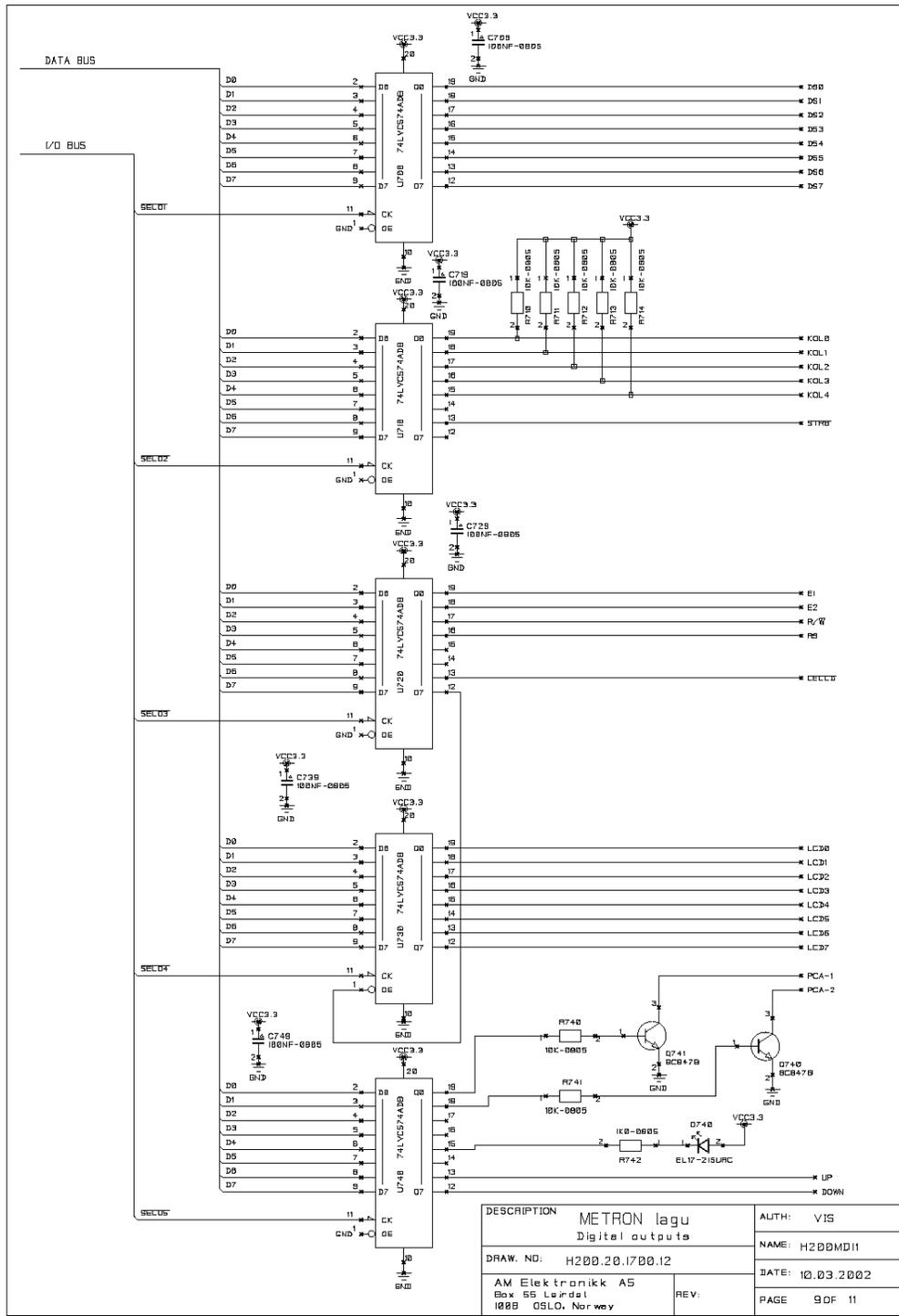
DESCRIPTION	METRON lagu Pressure measurement	AUTH:	VIS
DRAW. NO:	H200.20.1500.12	NAME:	H200MD11
AM Elektronikk AS Box 55 Lørdal 1008 OSLO, Norway	REV:	DATE:	10.03.2002
		PAGE:	6 OF 11

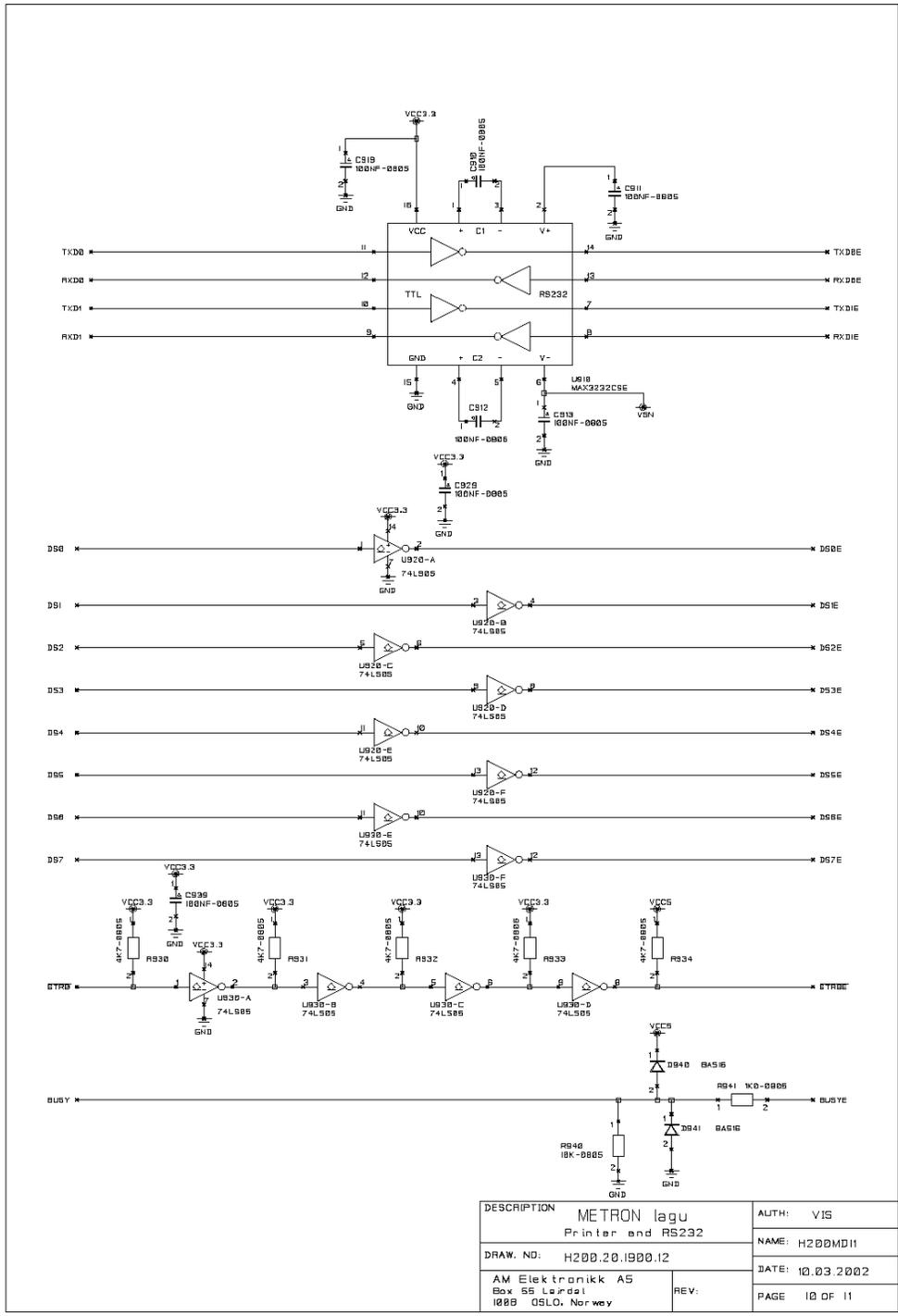


DESCRIPTION		METRON lagu	AUTH: VIS
		Digital I/O	NAME: H200MD11
DRAW. NO:		H200.20.1060.12	DATE: 10.03.2002
AM Elektronnikk AS		REV:	PAGE 7 OF 11
Søkk 55 teipdel 1088 OSLO, Norway			

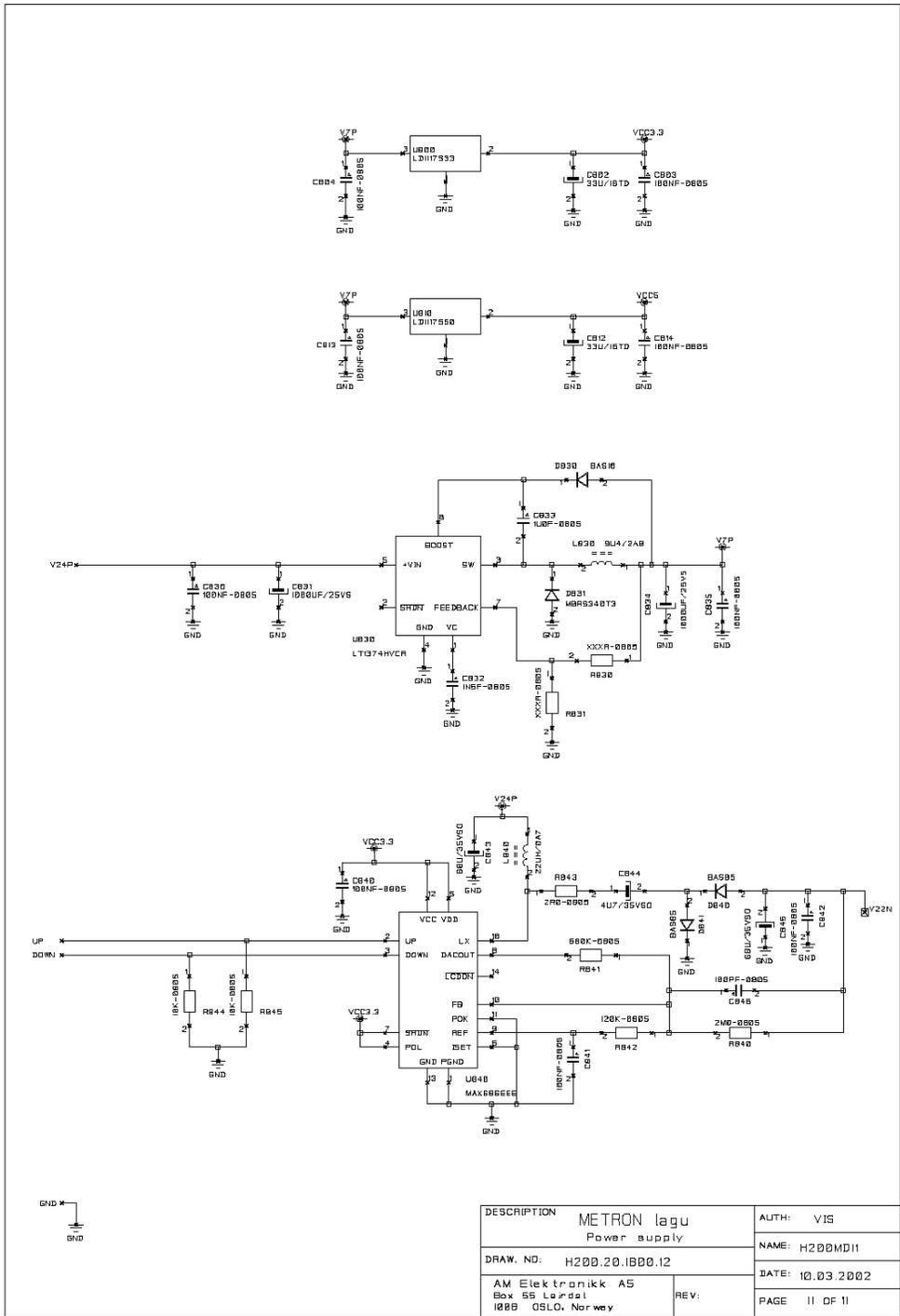


DESCRIPTION	METRON lagu Digital inputs	AUTH: VIS
DRAW. NO:	H200.20.1600.12	NAME: H200MD11
AM Elektronikk AS Box 55 Lørdal 1008 OSLO, Norway	REV:	DATE: 10.03.2002
		PAGE 8 OF 11





DESCRIPTION		METRON lagu		AUTH: VIS	
		Printer and RS232		NAME: H2DDMD11	
DRAW. NO:		H2DD.20.1900.12		DATE: 10.03.2002	
AM Elektronik AS		REV:		PAGE 10 OF 11	
Box 55 Lippo 1					
1888 OSLO, Norway					



DESCRIPTION	METRON lagu Power supply	AUTH: VIS
DRAW. NO:	H200.20.1B00.12	NAME: H200MD11
AM Elektrikk AS Box 55 Lørdal 1080 OSLO, Norway	REV:	DATE: 10.03.2002 PAGE 11 OF 11

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