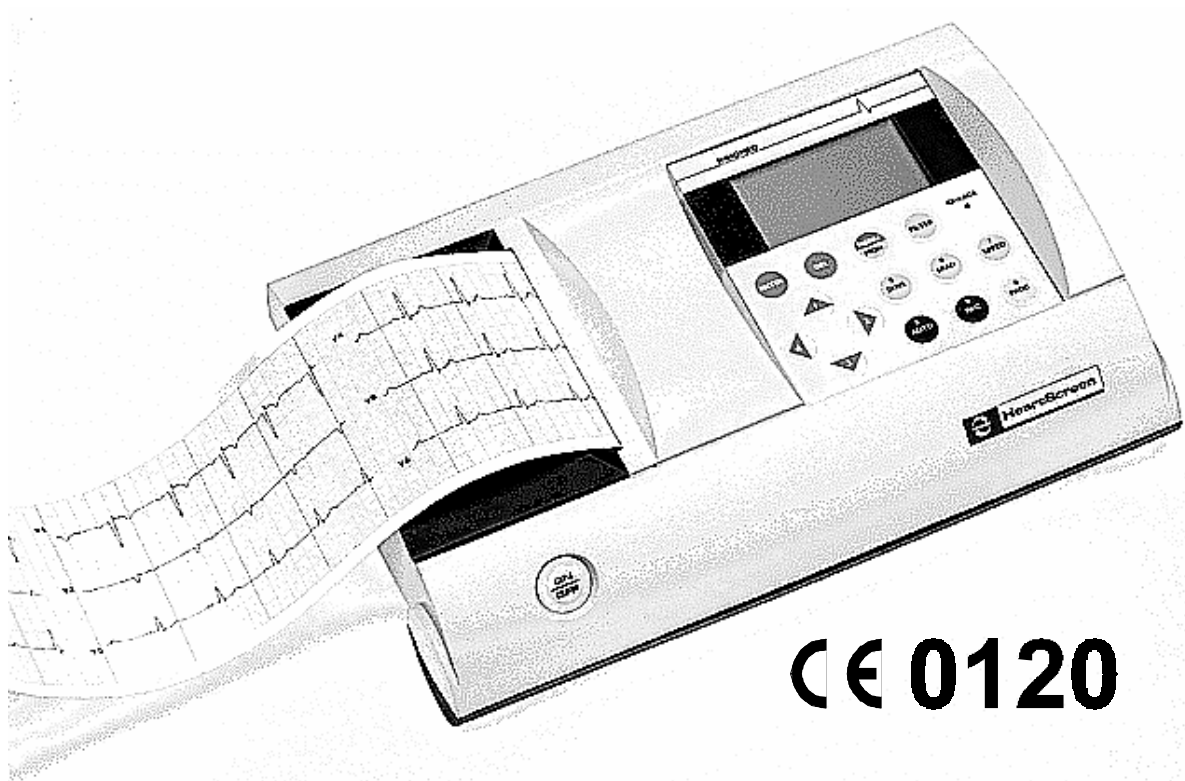


Service Manual

Heart Screen 80 G



Simultaneous 12-channel ECG device with 80mm wide
3-channel built-in printer and
LCD display

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2 Areas of use

The HeartScreen 80G is a battery-operated, modern 12-channel electrocardiograph, used to measure and graphically record the heart's bioelectric potential during human heart and circulatory system examination. The device contains a 12-channel amplifier and ECG signal-processing unit. The built-in printer is 3-channel. The high-speed 12-channel data transfer over the serial line insures 12-channel on-line display on the PC.

Operation of the device is simple, selecting the basic functions and the pre-edited record modes, and creating and storing the records need but a few button presses. Dedicated buttons can control the main functions, and the device returns the settings in the bottom row of the display.

Even in its basic configuration the device can be connected to a computer. On-line display of the selected 12 channels and record storage is possible on the PC's large display. The records stored in the HeartScreen 80G are identified by the date and exact time, and also by the automatically generated identification code or manually entered patient code.

The ECG management program, running under the Windows operating system, performs archiving and is useable with other INNOMED manufactured devices.

HeartScreen is available with the following services and configurations:

- **„A” version** – basic configuration features
3-channel recording in manual or automatic mode, built-in analysis and diagnosis program, built-in clock and battery pack.
- **„B” version**
All the features of „A” version expanded with built-in pulseoxymeter module.
- **ECG management program**
Optional with the above versions
IBM-PC based archiving program system. Can be used for on-line ECG monitoring, ECG and diagnosis storage, search and display. The program runs under the Windows operating system.

Manufacturing and distributing by:



Innomed Medical
Medical Developing and Manufacturing Inc.

✉ H-1146 Budapest, Szabó József u. 12.

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E-mail: innomed@innomed.hu

www.innomed.hu

3 *technical parameters*

Classification according to EC directives: 2a

Applied standards:	IEC 601-2-25	functional
	AAMI EC11	functional
	IEC 62D	functional
	IEC 601-1	safety
	EN 60601-1-2	EMC
	IEC 61000-4	EMC
	IEC 68-2-6	mechanical vibration
	IEC 68-2-29	mechanical shock
	93/42/EEC	medical directives

3.1 *General*

Reference temperature range	0... +40 °C
Operating temperature range	0... +45 °C
	20... 95% humidity (without condensation)
Shipping / storage temperature range	-20 ... +55 °C
Operating area	dry, confined place

3.2 *Mains and power supply*

Mains voltage	220V –10 %...230V +10%
Mains frequency	50 / 60 Hz
Power consumption	max. 23 VA
Current consumption	max. 170 mA
Accu type	5 NiCd accu pack, with 2000 mAh capacity
	6.2 V voltage
Accu charging current (information)	270 mA, not controlled
Accu charging time	30 minute periodic ECG curve printing or 4 hours monitoring (only basic functions operate)

3.3 *Safety*

Safety class	I.
Patient protection (with PC connection, too)	CF

3.4 Operating modes

MON	1-channel monitoring from any lead, including SPEC group.
REC	Manual recording from any lead group on 3 channels, including SPEC group.
AUTO	Adjustable record length from the 12 standard ECG leads, then automatic printing in 4x3 channel group.
PROG (STORE)	Automatic recording and storage from all groups, including SPEC group. Rhythm curve may also be stored in pre-programmed mode.
PROG (DIAG)	Automatic 12-channel recording with analysis and diagnosis. Raw curve, rhythm curve and SPEC group may also be stored in pre-programmed mode.
CAT	Catalog mode for stored record list and search.
SETUP	Device operation mode, default settings and program editing.

3.5 Lead groups

Lead groups

Standard groups		3 channel: I-III, aVR-aVF, V1-V3, V4-V6
SPEC lead group	<i>first</i>	any lead from the standard 12 or pulse curve
	<i>second</i>	any lead from the standard 12
	<i>third</i>	any lead from the standard 12

3.6 ECG amplifier

Input signal range (!)	± 10 mVpp
Frequency run	0.05 Hz...150 Hz +0,-3 dB
Voltage measurement relative error (!)	
0,5 - 5,0 mV	± 3 %
Sensitivity	2.5, 5, 10, 20 mm/mV
Sensitivity adjustment error	± 3 %
Noise referring to input	max. 20 μ Vpp
Input impedance (information)	min. 20 MOhm
Max. signal change speed (!)	min. 4 mV/10ms
CMRR	min. 100 dB
DC tolerance	min. ± 320 mV DC
Pace-maker tolerance	max. 700mV/2ms
Pace-maker detection	min. 2mV/0.5ms max.700mV/2ms
Time constant	min. 3,2 sec
Patient leakage current	max. 10 μ A
Blocking	automatic and manu
Calibration (software generated)	automatic, 10mm/mV
Muscle filter	35 Hz +0/-3 dB
Mains filter	50 / 60 Hz digital
- 20 dB points	50 Hz filter: 48,5 ... 51,5 Hz 60 Hz filter: 59 ... 61 Hz
Defibrillator tolerance	Max. 400 J, 5000 V
<i>Only with defibrillator protected cable!</i>	

3.7 Digitizing properties

Data collection	12 leads, simultaneous
Sampling frequency	1000 Hz / channel
A/D resolution	13 bit
Referring to ± 10 mV signal range	2.5 μ V/bit
Stored signal resolution	500 Hz
	10 μ V/bit
Serial line resolution during on-line ECG transfer	500 Hz
	10 μ V/bit

3.8 Printing and display properties

Effective recording width per channel	40 mm, overlapping allowed
Printer head resolution	in amplitude direction: 8 points / mm on the time axis: 16 points / mm
Paper speed	5, 25, 50 mm/s on-line
Paper speed adjustment accuracy (!)	$\pm 2 \%$
Paper width	80 mm +0; -1 %
Paper roll outer diameter	max. 50 mm
Printer lifetime	50.000 m
Paper change	automatic change
Display	64 x 128 points

3.9 SIO parameters

Serial I/O	standard RS - 232 +/-12V output min. +/-5 V input
Serial line services	on-line monitoring from the 12 channels ECG curve archiving on the PC

3.10 Mechanical vibration

Vibration protection	10 Hz...55 Hz, 0.3 mm amplitude 55 Hz...150 Hz 2g acceleration 20 cycle, 1 octave / min
Shock protection	40 g, 5 ms, 1000 cycle

3.11 Electromagnetic compatibility

Conducted and radiated noise	According to standard
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3.12 Mechanical data (information)

Size	310 * 265 * 70 mm
Device weight with battery pack and charger	1.2kg

3.13 Pacemaker pulse detection

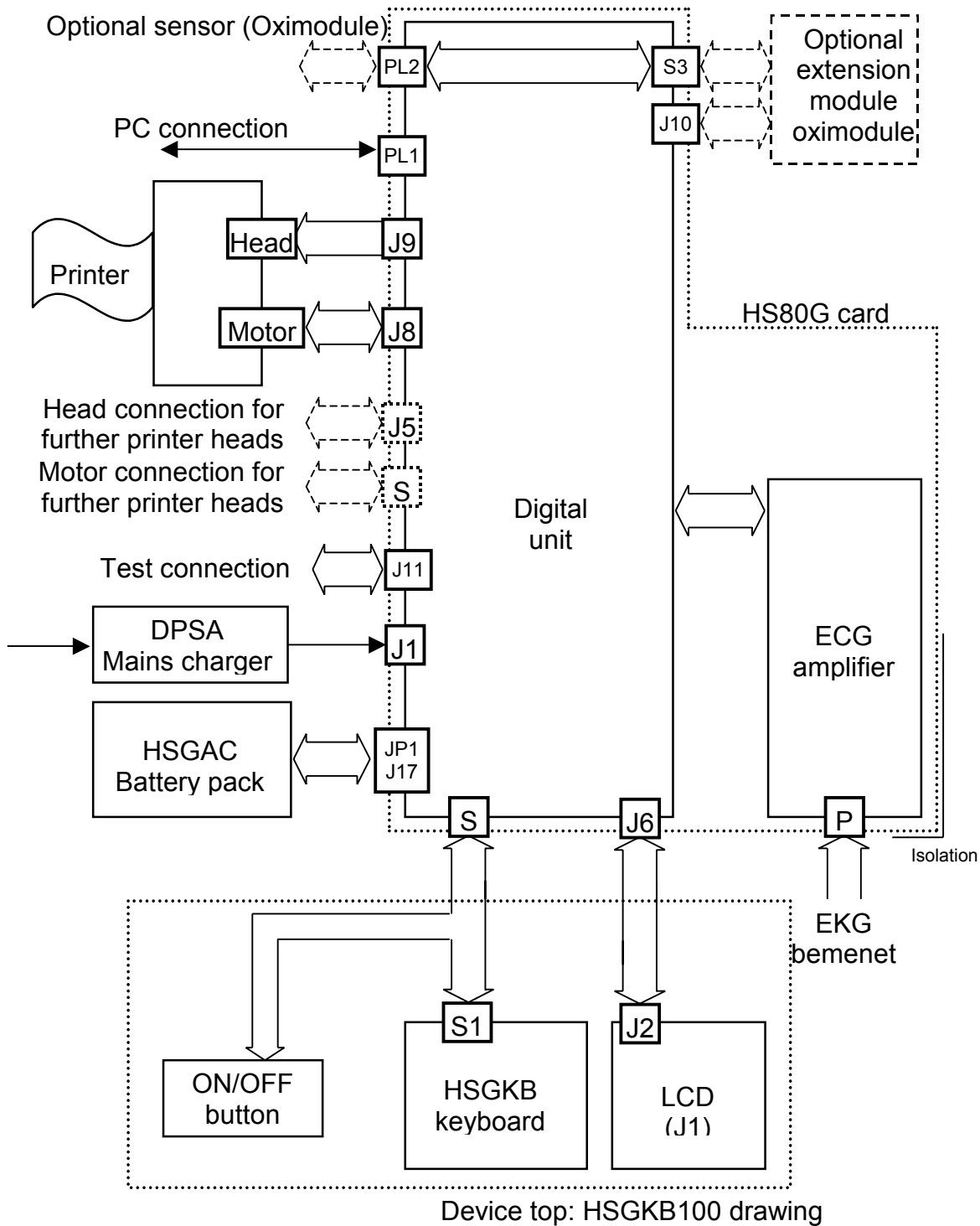
When the device examines a patient with a pacemaker, it recognizes the pacemaker signal within a set range according to technical data and displays them graphically on the record. In this case, the device does not create a diagnosis, since the pacemaker pulse interferes with the diagnosis program. If a diagnosis is needed in this situation, the device will indicate that a pacemaker pulse is on the signal.

3.14 Checking electrode and amplifier operation

If the input side of the amplifier does not work properly, the device blocks automatically.

4 Device components and their operation

4.1 Device block diagram of complete configuration:



4.2 HS80G card ECG amplifier unit

(HS80G110.sch)

4.2.1 Main functions as grouped by the connection diagram:

1/6. ECG input

This is where the device's ECG input circuits and the main amplifier levels with some of the error handling circuits. Further, this is where the multiplexer (U28) selecting the channel for the AD converter is located.

2/6. Overload Circuits

The pace checking and latch-up checking circuit input, signal preparation levels.

3/6. Filter

Contains the filter circuits with the connecting and blocking circuits.

4/6. ECG AD

This is where 13-bit AD converter (AD1), the reference-voltage creating circuit (OP2), the amplifier controller (U20) and the processor isolating circuits (OP1-OP4-Q2) are located.

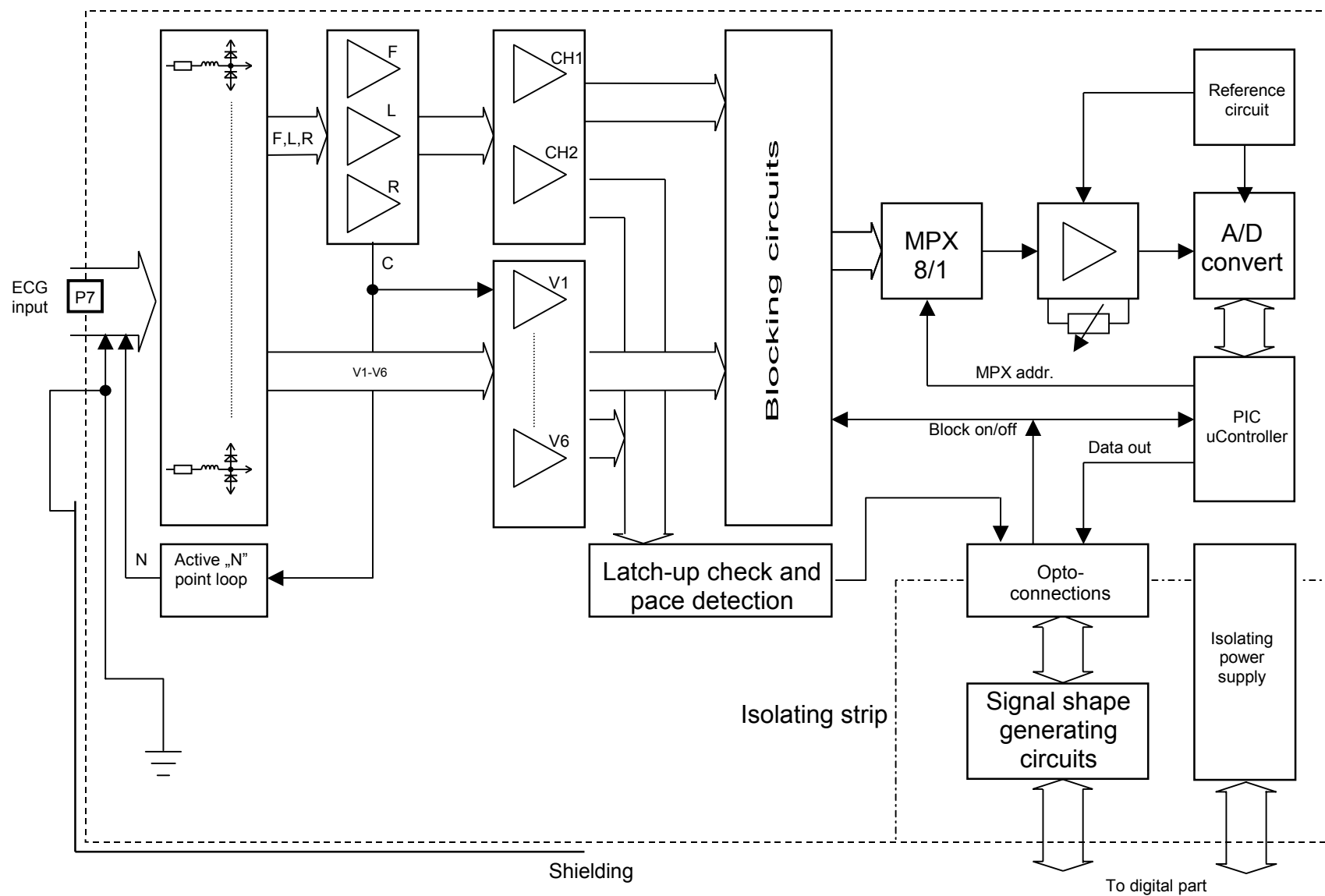
The two monostable circuits in U10 perform the combined latch-up / pace signal shape forming.

The two monostable circuits in U23 extract the auxiliary signals which belong to the ECG data pockets (Clock, Data ready/DMA request).

5/6. Isolated power supply

Contains the isolated switching power supply, which, besides the basic voltage, creates the negative voltage needed for the LCD contrast.

4.2.2 EKG amplifier unit block diagram:



4.3 HS80G card digital part

(HS80G110.sch)

4.3.1 Main functions according to the connection diagram:

6/8. Processor

Among other things it contains the microprocessor (U24), the 128kByte external RAM (U29), the calendar IC (U21 RTC), and the serial digitized ECG signal receiveing readable 2 8-bit registers (U37 and U39). All these connect to the common 8-bit data and 19-bit address bus.

However, the display's connection (J6) and the keyboard's connection (S6) connect directly to the processor's (U24) I/O pins.

The circuit that creates the -7.2V contrast voltage for the display can also be found here (U42,U48B).

The possible expansion card (for example oxymeter module) can connect to the processor through the J10 connection. The expansion card's external rear connection (PL2) operates through the S3 – by default – not inserted holes. PL2 is inserted in the basic model as well, but is unused.

7/8. Printers

This side contains the controled power supply (IRF4905, U43A, OP3), which ensures printer power directly from the battery.

The control bytes transferring the burning pixels serially to the printer head originate from the U46 IC, and the clock signal from the U45 IC. The U46 IC connects to the processor bus.

The burn controller, burning time controlling circuit (U44B) and the printer head power supply switching circuit (U44A) is also here.

The processor directly controls the motor control IC (U41).

We ship the device with an 80 mm LTP3345 head (connection points J8-8), but other head types can also be connected through the J5 and S5 connections (these are not inserted).

8/8. Power Supply

The most important of these circuit blocks is the U38A-U51A-T2 trio, turning the device on and off.

Beside them is the U92 bus switch, which controls the speaker and the automatis shut-off feature.

This is where the circuit creating the reference voltage required by the device's dgital circuit parts (U43A).

U11 ensures the voltage for the digital circuits.

When connecting a charging adapter, the charging circuit contains a continuously operating current generator (U35-R108-R17).

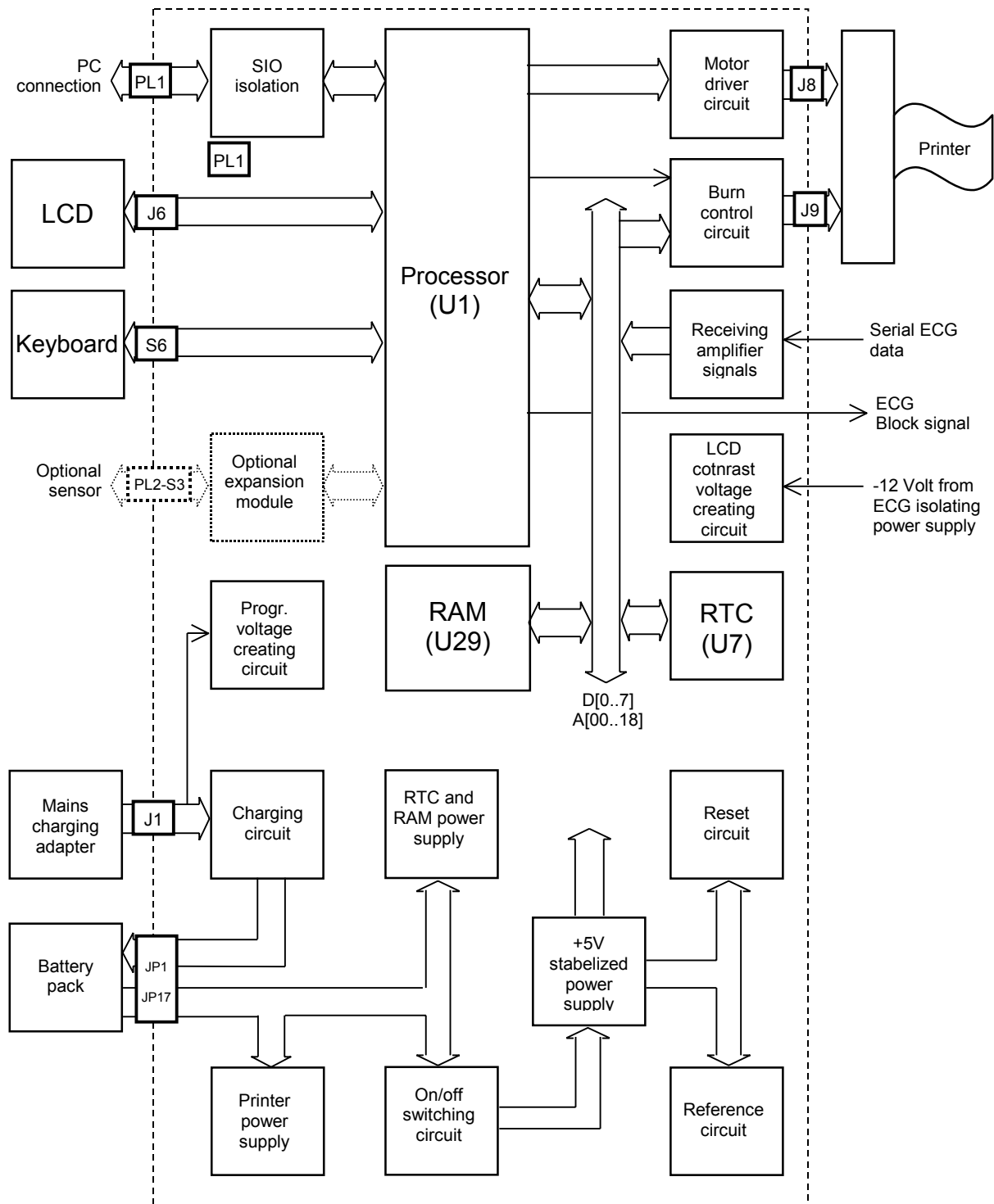
The reset signal generating circuit (U5), the voltage generating circuit required for reprogramming (U31) and the programming control reed-relay (JP7) can also be found here.

A separate circuit is there to supply the RAM for stored records and the clock-IC with power when the device is shut down, by draining the battery (J17).

The test connection (J11) is also located here, as well as the circuit making it possible for the processor to measure the battery voltage (R260-261).

The largest circuit block on this side is the circuit ensuring PC serial transfer. The main parts of the circuit are the safety power supply (U86-TR2) and the opto-connectors realizing two-way connection (U80-81). The power supply automatically turns on and off to serial line signal from the PC, can be switched from the device with one of the processor output ports.

3.3.2. Digital part block diagram:



4.4 Keyboard and the LCD

(HSGKB101.sch)

Shows the device membrane keyboard's connection diagram with the device power switch, and the LCD connection.

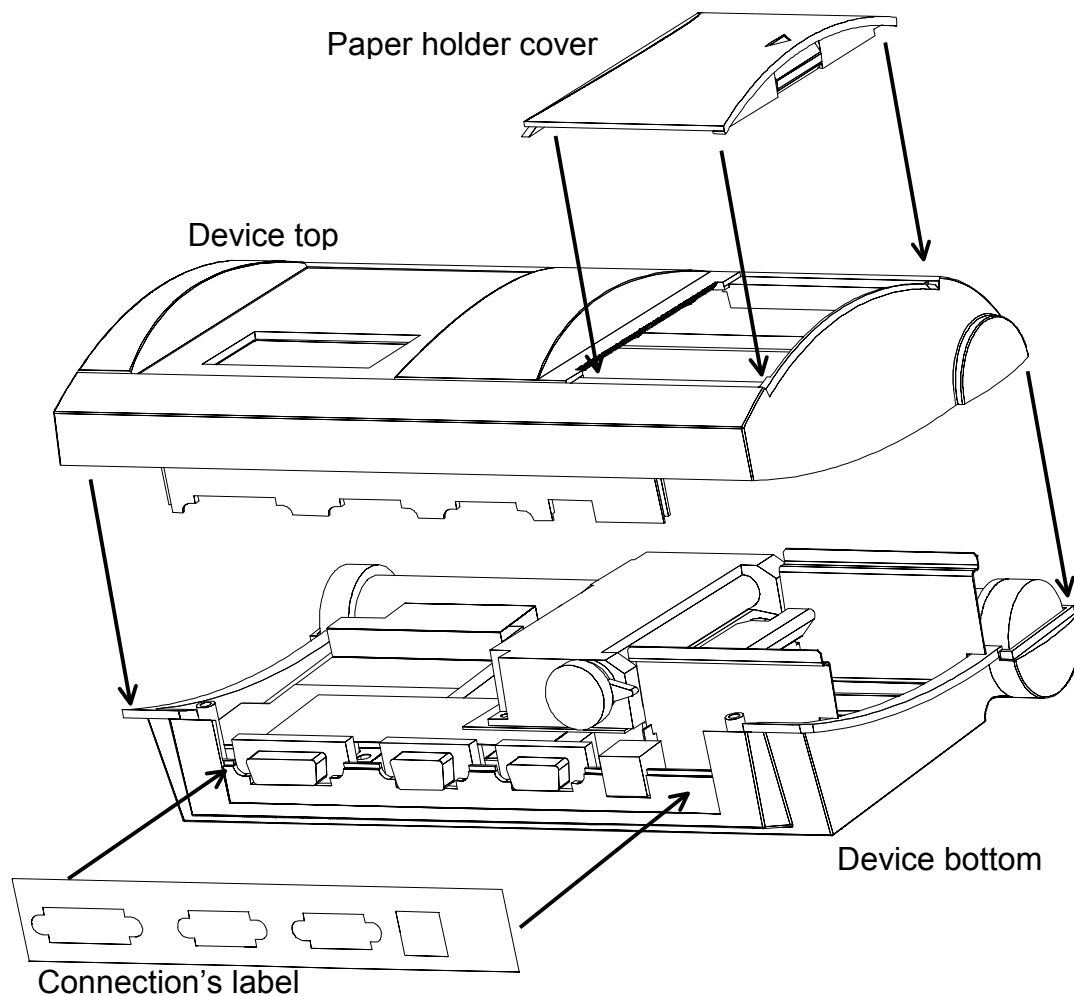
4.5 Battery pack

(HSGAC101.sch)

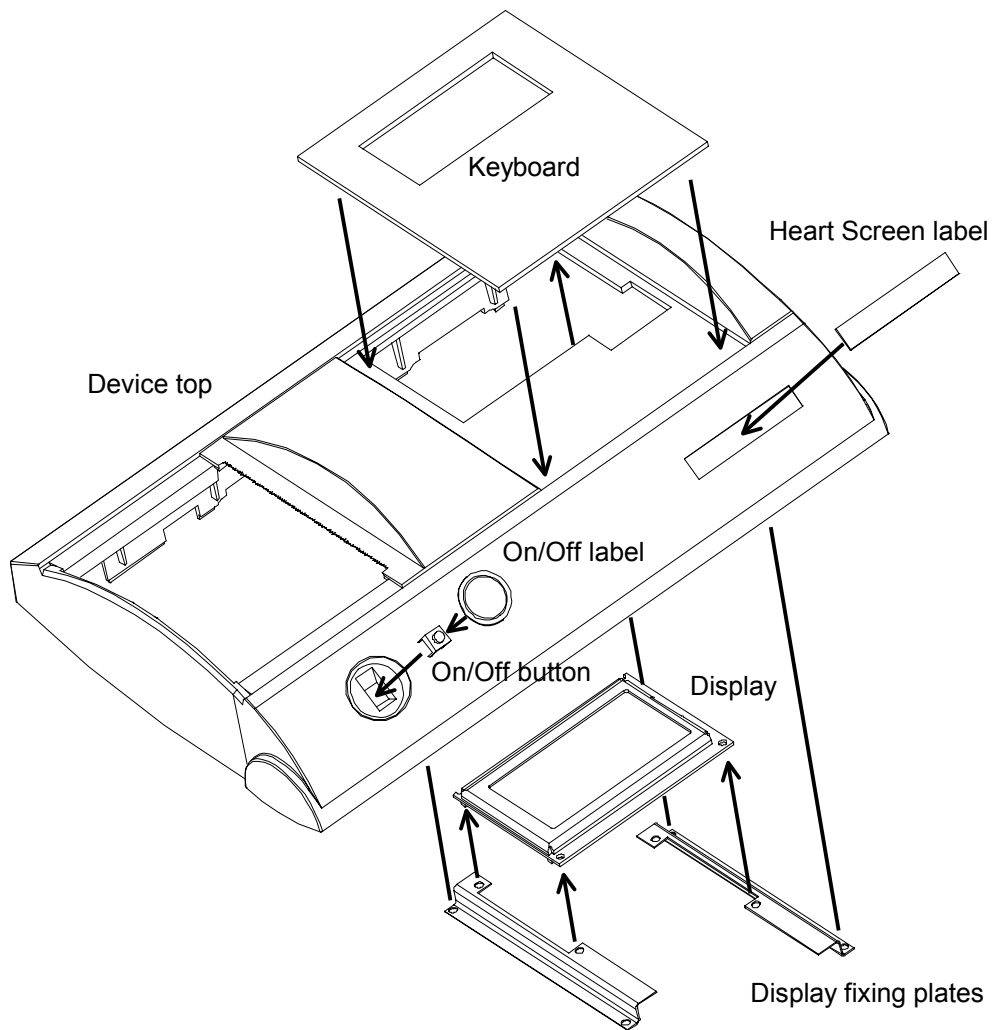
The battery pack contains 5 2000 mAh rechargeable batteries. The pack is drained at the third cell. This output supplies the clock chip and the record storing RAM with power when the device is turned off.

4.6 Device mechanical construction

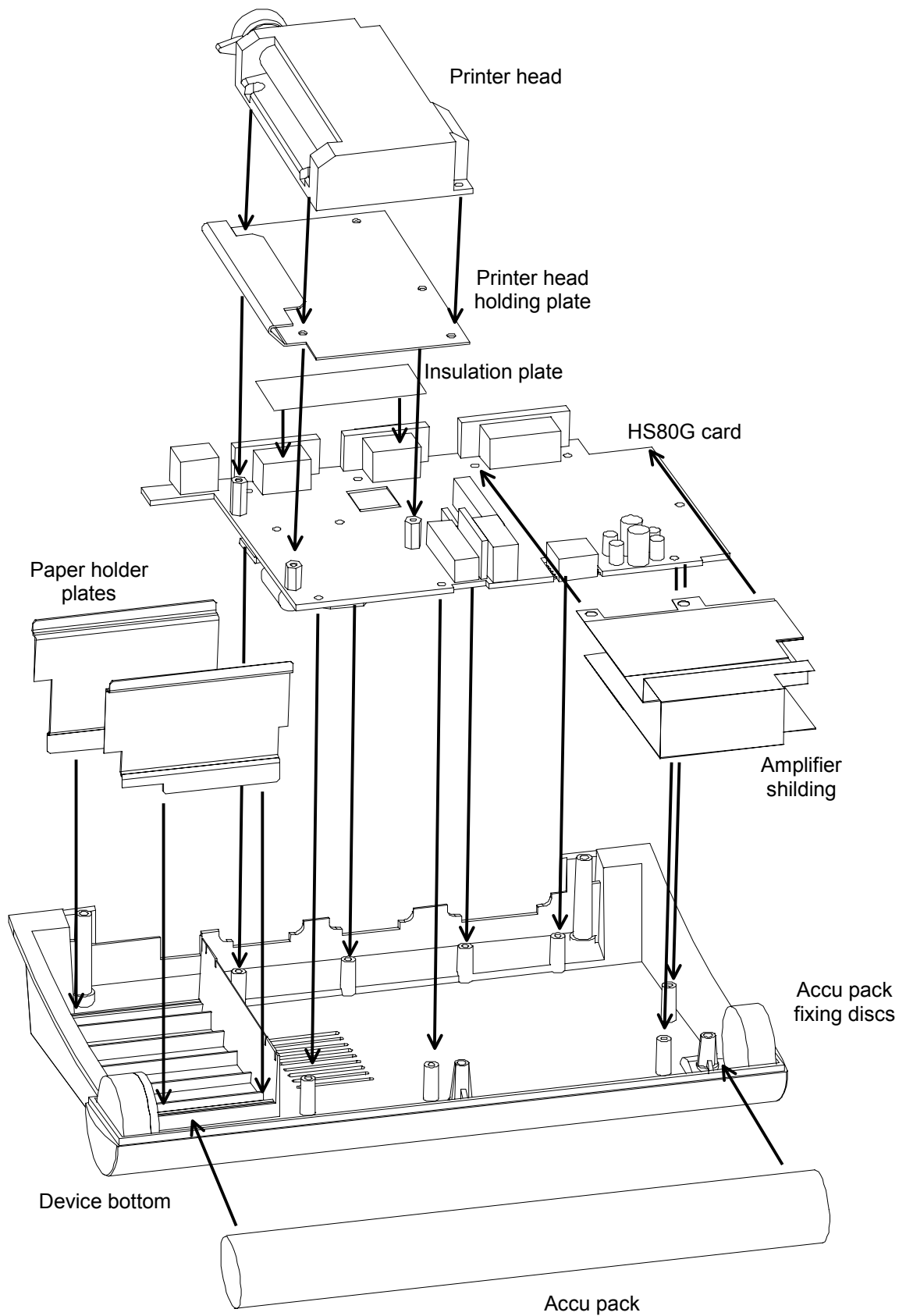
4.6.1 Device summary



4.6.2 Device top mechanical construction



4.6.3 Device bottom mechanical construction



5 Possible errors and troubleshooting

Problem	Possible causes	Solutions
When connecting the charger to the mains, the „POWER ON“ LED is not on and the appropriate voltage cannot be measured on the output.	<p>One of the fuses in the charger adapter has burned out.</p> <p>The adapter cable of the connection is damaged.</p> <p>The mains voltage is not appropriate.</p> <p>Switching power supply is damaged.</p>	<p>Change the fuse and find the reason for the burn-out.</p> <p>Check the charging adapter and the connection.</p> <p>Check the mains voltage.</p> <p>Change the power supply.</p>
The „CHARGE“ LED is not on after an operational charging adapter is connected.	<p>The adapter cable or connection is damaged.</p> <p>The keyboard connection is not satisfactory.</p> <p>The keyboard is damaged.</p> <p>The charging circuit is damaged.</p>	<p>Check the charging adapter cable and connection.</p> <p>Check keyboard connection.</p> <p>Check the „CHARGE“ LED on the keyboard.</p> <p>Check the charging circuit.</p>
The device turns off immediately after turned on.	<p>The battery has discharged.</p> <p>The charging circuit is damaged.</p>	<p>Recharge the battery.</p> <p>If this occurs after recharging, check the charging adapter and the charging circuit, according to the documentation.</p>
After the device has been turned on the software does not start at all (only the display's change in tone indicates that the device is on, nothing is on the display).	<p>The battery has discharged or the charging circuit is damaged.</p> <p>The soldering is not satisfactory.</p>	<p>Charge the batteries.</p> <p>If this occurs after recharging, check the charging adapter and the charging circuit, according to the documentation.</p> <p>Check the soldering on the digital part of the HS80G card. Resolder the IC's with the exception of the processor.</p> <p>If it cannot be repaired, replace the card.</p>

Problem	Possible causes	Solutions
The device does not turn on.	<p>The batteries are completely discharged.</p> <p>The battery-protecting fuse has burned out.</p> <p>The battery is damaged.</p> <p>The cable to the power switch is damaged.</p> <p>The connection to the power switch has slipped off.</p> <p>The soldering is not satisfactory.</p>	<p>Check the battery and its charge state, and the fuse.</p> <p>In case of replacing the fuse, try to find the reason for the burn-on and fix it.</p> <p>Check the battery.</p> <p>If it cannot be fixed, replace it.</p> <p>Check the cables and the connections.</p> <p>Check the soldering on the digital part of the HS80G card. Resolder the IC's with the exception of the processor.</p> <p>If it cannot be repaired, replace the card.</p>
The keys or at least some keys are not operational.	<p>The cables are not connected or are damaged.</p> <p>The keyboard card,</p> <p>or the HS80G card is damaged.</p>	<p>Check the cables and connections.</p> <p>Check the keys according to the connection diagram.</p> <p>If any of them are damaged, replace the keyboard.</p> <p>Check the HS80G with another keyboard.</p> <p>Check the soldering and the keyboard control signals on the HS80G card.</p> <p>If it cannot be repaired, replace the HS80G card.</p>
The device cannot be reprogrammed.	<p>The reed-tube in the device is broken (cannot switch to boot mode with the magnet at the specified place in the device).</p> <p>The serial cable is damaged or incorrect PC serial port setting.</p> <p>The charging adapter is damaged.</p>	<p>After disassembling the device, check the tube. If necessary, replace it.</p> <p>(If no replacement tube is available, temporarily reconnecting the reed-tube places the device into programming mode.)</p> <p>Check the serial cable and the PC, and the download software settings.</p> <p>Check the charging adapter.</p>

Problem	Possible causes	Solutions
When turned on, the device always starts with a memory error.	Soldering is not satisfactory. The battery, or its cable to J17 is damaged.	Check the soldering on the digital part of the HS80G card. Resolder the IC's with the exception of the processor. If it cannot be repaired, replace the card. Check the battery. If it cannot be repaired, replace it. Check battery cabling.
Serial line connection is not working.	The Innobase or device software version is not appropriate. PC settings are not appropriate. The serial cable is damaged. The device's serial line circuit is damaged.	Check the Innobase version (at least 1.2.) and the Innobase software module version (at least 1.1). Check the device software version (at least 1.24) Check PC settings, the serial cable, and the device serial circuit.
A single ECG channel is noisy.	A single line in the cable or the isolation is broken.	Replace the patient cable.
Several ECG channels are noisy.	The environment noise is too great, the mains ground protection conductor is damaged, or the amplifier is generating.	Check the environment for electromagnetic noise. Check the mains ground protection conductor continuity to the device charging adapter connection input point (-). Check and repair the amplifier card according to the documentation.
The mains filter (50 or 60Hz) has no effect.	The noise is not appropriate for the mains frequency or environment noise is too great.	Software based filter malfunction is not likely. Check the mains frequency and the environment for electromagnetic noise.
Baseline movement is too great.	The amplifier's too great time constant and high-impedance parts can be a source of the problem; it is possible, that the multiplexers before the ADC or the DC isolating capacitors are damaged. May also be caused by condensing humidity.	The baseline can be within +/- 1mm on a 10-second recording. Check and repair the amplifier card according to the documentation. If necessary, replace the HS80G card. Check if it was caused by condensing humidity.

Problem	Possible causes	Solutions
The printed curve is missing along a horizontal line.	The printer head is dirty or a pixel has burnt out on the burning head.	Clean the printer burning head with alcohol. If this does not solve the problem, replace the entire printer head.
Although paper is loaded, the printer does not print.	Incorrect paper position or the head-lifting lever is in incorrect position.	Check that the head is not lifted off the paper and the paper is in the correct position.
Parts of the printed picture are faded.	The rubber roll does not tighten evenly on the burning head; problem with paper quality or burning voltage.	Check paper quality, and the burning voltage (HEAD_POWER) and burning time. In case of printer head problem, replace it.
The foil has come up on the keyboard or the power switch.	Gluing has become loose.	Replace the keyboard or the foil.
The circuit board supporting the keyboard foil has come up.	Gluing has become loose.	Completely disassembling the top part of the box, re-glue the keyboard.
The paper bin is too tight sideways, the paper roll does not fit.	The plates in the paper bin are in incorrect position.	Disassemble the device and – when re-assembling it – position the plates in the paper bin according to the mechanical drawings.

6 Card level measurements

6.1 Checking battery charging

Connect a 6V power supply (with max. current limit) to the battery connections in parallel with a 10 Ohm/5W resistance. Connect a 15V/11A power supply to the charging adapter connections. The device must be turned off, but connect the keyboard. Measure the current flowing through the battery connections and the charging adapter. During charging the keyboard's "charge" LED must be on.

Measurement point	Nominal value	Tolerance	Comment
JP1.2	272 mA	+/-30mA	Battery-current
J11.9	272 mA	+/-30mA	Charging adapter current
D2 cathode	+12.3V	+/-0.3V	Prog. voltage
Keyboard LED	On		

6.2 Checking voltages – digital circuits

Connect the power supply set to 6V/1A in place of the battery and turn the device on. Check the following signals:

Measurement point	Nominal value	Tolerance	Comment
J11.9	5.95V	+/-0,1V	ONPOWER
J11.1	+5V	+/-0,1V	+5V
J11.3	Min. 100 ms		RESET 90% of run-up edge compared to J11.1
J11.3	Max. 1 ms		RESET run-down compared to J11.1 When turned off, the signal must be less than 0.5V.
J11.2	14,7456MHz		Clock signal (enough if it is clearly visible +/- 10%)

6.3 Checking voltages – SIO

Turn on the device running from 6V (battery voltage) with C53 shorted or 5-10 seconds after the device has been turned on measure the automatically switching off voltages.

Measurement point	Nominal value	Tolerance	Comment
U80.8	+12.5 V	+/- 1V	+SIO power
U80.7	-12.5 V	+/- 1V	-SIO power

The SIO part's GND signal can be reached on pin 5 of the PL1 connection.

After setting remove the short. The voltages may be set with R235 and R113.

If the voltage is low, it is useful to put 18K in place of R113. in case of high voltage, 47K-220K value must be soldered onto R235.

6.4 Checking voltages – ECG side

Turn on the device, running from 6V (battery voltage). Connect short on the ECG input. For ECG side measurements the GND JN1 is the short.

Measurement point	Nominal value	Tolerance	Comment
D46 cathode (+VCCAN)	+7V	+/-0.3V	The analog power is to be set with P14, in case of raw setting, use R51.
D47 anode (-VCCAN)	-7V	+/-0.3V	
J11.7	-7.4V	+/-0.2V	Contrast voltage, set with R198 (if too positive, must be changed to larger).
AD1.10	2.048V	+/-5 mV (!)	Reference, set with P8-al (digital side!)
U20.2	+5V	+/-0.15V	Digital power on the ECG side.
J11.5	Data signals with 4 µsec clock signal	+/-0.2 µsec	Check data signals 16 / packet, repeating time 125 µsec.
U37.3	4 µsec clock signal with 50% divide ratio	+/-10% divide	Check (if necessary, set with R78)
JP1.2	6.4.1.1.1 Max. 210 mA		Battery consumption (when SIO turned on / marked with an * / 260mA)

6.5 ECG part test

6.5.1 Offset measurement

To set the offset, connect the patient cable and short all the electrodes. Set the device to maximum sensitivity (x2) and 25 mm/sec speed. Start continuous monitoring and give a BLOCK command.

Step the lead selector over the I, II, V2...V6 leads and measure the zero line. Find the channels with the greatest positive and negative offsets. The measured offsets are +DCmax and -DCmax. Using the P20 potential meter set the offset so the

$$|+DCmax| - |-DCmax| = 0 \text{ equation holds true.}$$

The tolerance may be +/- 100 µV at most, which means 2mm on the printout at 2x sensitivity.

6.5.2 Amplification setting and DC tolerance measurement

Apply (16000 +/-0.5% µVpp / 10Hz sine) + DC signal on the amplifier input according to the tables from a ground-independent generator. DC size should be 0, +320, -320 mV.

Set the device to 2 mV/cm sensitivity (x1/2) and 25 mm/sec speed. With the lead selector start all the channels and measure the signal amplitude.

Select the largest and smallest amplified channels, and have the measured amplitudes be Umax and Umin. Set the amplification with the R155 and R157 resistors so the

$$(Umax - Umin) / 2 = 16000 \mu V \pm 80 \mu V (\pm 0.5\%) \text{ equation holds true.}$$

After the amplification setting perform the following checks.

a/ In case of DC = 0

The signal's amplitude on the measured lead should be $16000\mu\text{V} \pm 320\mu\text{V}$ ($\pm 2\%$).

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

b/ In case of DC = -320 mV

The signal's amplitude on the measured lead should be $16000\mu\text{V} \pm 320\mu\text{V}$ ($\pm 2\%$).

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

c/ In case of DC = +320 mV

The signal's amplitude on the measured lead should be $16000\mu\text{V} \pm 320\mu\text{V}$ ($\pm 2\%$).

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

6.5.3 CMRR check

For CMRR setting connect the patient cable and short all the electrodes except for the "N" point. Apply a 1Vpp +/-0.5% amplitude 50Hz sine signal between the amplifier's ground point and the shorted electrodes. Set the device to the highest, 0.5mV/cm sensitivity (x2) and 25 mm/sec speed. With the channel selector monitor all the channels one-by-one.

During monitoring measure the signal on the AD input (AD1.5 pin) with a scope by synchronizing it to the CH3MPX (U20.15) signal. The eight channels' phases must be visible on the scope. The individual phase's time is 125 µsec. During continuous monitoring try to decrease the error signal with P6-and resistor R176 so approximately the same error signal is generated on all the channels. Watch the error signal on the scope.

The CMRR is acceptable is the measured amplitude is less than 250 µVpp, or 74 dB.

P1	P2	Measured lead
N	all other	I
N	all other	II
N	all other	V1
N	all other	V2
N	all other	V3
N	all other	V4
N	all other	V5
N	all other	V6

6.5.4 Checking blocking

For the measurement connect the patient cable and short all the electrodes with the exception of the "R" lead. Apply +320 mV DC voltage between the "R" lead and the other leads. Set the device to highest, 0.5mV/cm sensitivity (x2) and 25 mm/sec speed.

Monitor all the channels one-by-one during continuous monitoring. During monitoring give a blocking command. After blocking the signal must remain within 100 µV. Allow the signal to run for at least 10 seconds on all the channels after blocking, the baseline must remain in the +/-100µV range all along.

Repeat the measurement with -320 mV DC as well.

6.5.5 Checking frequency transfer

Apply (16000 +/-0.5% µVpp / 150Hz sine) + DC signal on the amplifier input according to the tables from a ground-independent generator. DC should be +320, -320 mV. Set the device to 4mV/cm sensitivity (x1/4) and 25 mm/sec speed.

Connect the patient cable according to the following tables, start the individual channels with the channel selector and measure the signal amplitude.

a/ In case of DC = -320 mV

The signal's amplitude on the measured lead should be at least 11200µV.

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

b/ In case of DC= +320 mV

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

6.5.6 Checking time-constant

Apply (8000 +/-0.5% μVpp / 0.05 Hz sine) + DC signal on the amplifier input according to the tables from a ground-independent generator. DC should be +320, -320 mV. Set the device to single sensitivity (x1) and 5 mm/sec speed. Filter is off.

Connect the patient cable according to the following tables, start the individual channels with the channel selector and measure the signal amplitude. The time-constant should be at least 3.2sec:

a/ In case of DC = -320 mV

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

b/ In case of DC= +320 mV

P1	P2	Measured lead
L	all other	I
R	all other	II
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

6.5.7 Checking pacemaker detector

Warning ! With PACE generator measurements the system noise can be max. 0.5 mm!

Apply (2000 \pm 0.5% μ Vpp/10 Hz sine) + PACE signal on the amplifier input according to the tables from a ground-independent generator. PACE impulse amplitude should be 2mVpp, width 0.5ms, repeating frequency 1Hz.

Set the device to half sensitivity (x1/2) and 25 mm/sec speed.

Connect the patient cable according to the following tables, start the individual channels with the channel selector and measure the signal amplitude. Only the measurement order quality has to be checked on the monitor, meaning that the PACE impulse must appear on the 2mV amplitude sine signal. The PACE detector operation must be checked with the oscilloscope connected to the text connection's PACE output.

Active TTL level impulses must be seen at low level on the oscilloscope, which width is 100 (\pm 20 %) ms and appear with the PACE repeating frequency. The impulse widths can be set with R10 (if necessary, can be changed to 510K or 1M may be enough in parallel).

The PACE detector operation must be checked on all leads with both positive and negative PACE polarity. If the detector does not signal, the R90-94 or R88-95 resistance pairs can be used to slightly set the comparison level. If more serious modification is required, the level may be decreased with resistors, for example 47K, connected in parallel with R11-12-44-47-61-68-69-70 according to the channels.

P1	P2	Measured lead	Positive impulse pass	Negative impulse pass
L	all other	I		
R	all other	II		
V1	all other	V1		
V2	all other	V2		
V3	all other	V3		
V4	all other	V4		
V5	all other	V5		
V6	all other	V6		

6.5.8 Checking PACE tolerance

Connect only the PACE impulse generator to the amplifier's input according to the table. PACE impulse amplitude should be 700mVpp, width 2ms, repeating frequency 1Hz.

Set the device to the highest, 0,5mV/cm sensitivity (x2) and 5 mm/sec speed.

Connect the patient cable according to the following table and start monitoring the individual channels one-by-one, and then block the amplifier until the PACE signal arrives. On the monitor check the baseline shift due to the PACE impulse. 12ms after the PACE the baseline can shift max. 100 μ V compared to before the PACE. The baseline's long-term stability can be 6mm/30 sec (300 μ V/30sec).

During measurement the PACE detector operation must be checked with the oscilloscope connected to the test connection's PACE output. TTL level impulses must be visible on the oscilloscope, which width is 100 (+/- 20%) ms and appear with the PACE repeating frequency. The PACE tolerance and the detector operation must be checked on all the leads with both positive and negative polarity.

P1	P2	Measured lead	Measured differentiated error value (µV)		Measured long term error value (µV)	
			positive	negative	positive	negative
L	all other	I				
R	all other	II				
V1	all other	V1				
V2	all other	V2				
V3	all other	V3				
V4	all other	V4				
V5	all other	V5				
V6	all other	V6				

6.5.9 Checking amplifier latch-up watcher

Only connect the DC generator to the amplifier's input according to the table. The DC level has to be regulated between 0 and 500 mV.

Set the device to 1mV/cm sensitivity (x1) and 25 mm/sec speed.

Connect the patient cable according to the following table and start monitoring the individual channels one-by-one. On the monitor check the measurement order quality and the baseline, which can be reset with the blocking command after the DC regulation.

During measurement the latch-up watch circuit's operation has to be checked with the oscilloscope connected to the test connection's PACE output. The PACE output is continuously high if the circuit can handle the DC applied to the amplifier, and continuously low if the DC is overdriven. The comparison levels have to be at least 340 mV and 400mV.

If the levels are too high, they may be decreased by increasing R60-R67, and may be increased in reverse.

P1	P2	Measured lead	Positive DC (mV)	Negative DC (mV)
L	all other	I		
R	all other	II		
V1	all other	V1		
V2	all other	V2		
V3	all other	V3		
V4	all other	V4		
V5	all other	V5		
V6	all other	V6		

6.5.10 Noise measurement and baseline checking


Short all the inputs with a short-plug (without a patient cable) and measure the channels' noise with the measurement program running.

Set the device to the highest, 0,5mV/cm sensitivity (x2) and 25 mm/sec speed, with the filter off.

The noise cannot be greater than 20 µVpp.

6.6 Checking basic functions

1. Connect the keyboard, the LCD and the generator.
2. Before downloading the program connect a power supply set to +6V in place of the battery. Remove the resistor.
3. Connect the other power supply – set to 3.6V – to the J17 battery drain point. Connect the the negative points of the two power supplies.

Test procedure	Comment
Keyboard test	
Speaker test	During ECG signal monitoring, if the speaker is turned on.
RTC (clock) test	Set the exact date and time, and the device has to operate based on this date and time even after it was turned off and on again.
Contrast test	The LCD contrast is acceptable, not foggy, the LCD is operational.
Serial data transfer test	ECG signal monitoring with Innobase for Windows program and generator, checking main functions.
Serial data transfer test with SIO reducing cable	ECG signal monitoring with Innobase for Windows program and generator.
Low Batt. check	Continually decrease battery voltage and with it the ONPOWER voltage level (the processor checks this every second), at 5.65 +/- 0.1V in the bottom right corner a signal appears:  (ONPOWER J11.9)
Checking power off	Continue to decrease the battery voltage (the processor checks this every second), the device turns off at 5.1 +/- 0.1V (ONPOWER J11.9).

6.7 Checking printing

6.7.1 Printer partially connected

1. Compared to the previous point connect a 4700uF capacitor in parallel with the power supply (6V max. current limit), which is in place of the battery.
2. Connect the printer motor connection and load the paper. Connect a short on the ECG input.

Measurement place	Nominal value	Tolerance	Setting mode	Comment
J11.8	Max. 4.5msec		R228	Burn time (active signal at high level)
J11.10	+5V	+/-0.1V	R223, R224	Printer power

Between starting and stopping printing check the printer power supply's on and off transients:

Measurement place	Check criteria	Method of check and acceptance criteria
J11.10 (HEAD POWER)	Storage scope is required	J11.10 signal power-on overshoot can be max. +0.2V. Power-off transient cannot be, the signal must decrease monotonously.

6.7.2 Print test with printer

Connect the burning head as well and start 50mm/sec on-line printing. Watch the signal shape, that the displayed curves are continuous, there are no breaks, spikes, faded sections.

Further, measure the power consumption at the battery connection's negative point:

Measurement place	Nominal value	Comment
JP1.1	1-2.5 A fluctuating	Current from the battery

6.7.3 Checking ECG signal

When measuring with the Phantom 320 simulator, first the generator amplitudes must be defined with analysis with a certified device as a reference measurement. During the measurement series, compare to the reference.

At this point of the checks the analysis' QRS cycle's highest positive or negative wave's amplitude has to be checked, as well as the T-wave amplitude, on all leads. The values measured by the device can deviate max. 5% compared to the reference values.

6.8 Power consumption measurement

1. Connect the keyboard, the LCD and the short-plug.
2. Before downloading the program connect the power supply set to +6V in place of the battery. Remove the resistor.
3. Connect the other power supply, set to 3.6V, to the battery drain going to J17. Connect the negative points of the two power supplies.
4. Connect the printer and load the paper.

Measure the following parameters:

- Battery power consumption at JP1.1 (**negative pole!!**). Monitor ECG signal on the display. The measured current can be max. 200 mA (260mA in case of turned-on SIO).
- When the device is turned off, measure the power consumption at JP1.1 (**negative pole!!**). The measured current can be max. 10uA.

7 Device level measurements

In the following uncontrolled measurement procedures the IEC601/1 safety and the IEC 601-2-25 ECG device related standards are relevant.

7.1 Safety examinations

In case of repeated examinations the high-voltage sparking examination has to be performed with decreased voltage. In this case the voltages are at least 80% of the given value.

7.1.1 Sparking examination

High-voltage sparking examination has to be performed on the device with the following voltage values:

- 1.5 kVeff between the power supply's primary and secondary side
- 4 kVeff between the device's secondary side and the patient connection
- 4 kVeff between the charging adapter connection and the PC -SIO connection
- 4 kVeff between the patient connection and the PC-SIO connection

7.1.2 Leakage current measurement

Leakage current measurement during operation with 253 V examination voltage.

Measurement place	Allowed value / μA /
Between the mains pins and the protective ground	50
Between the mains pins and the patient connection	10
Between the mains pins and the PC SIO connection	10
Between the mains pins and the oxymeter connection	10

Leakage current measurement in case of 1 error with 253 V examination voltage.

Measurement place	Allowed value / μA /
Between the mains pins and the protective ground	100
Between the mains pins and the patient connection	10
Between the mains pins and the PC SIO connection	10
Between the charging adapter connection and the patient connection	10
Between the charging adapter connection and the SIO connection	10

7.1.3 Sensitivity examination and DC tolerance checking

Apply +DC signal according to the table from a ground independent generator to the amplifier's input (2 mVpp/10Hz sine). DC must be +320,-320 mV. Set amplifier sensitivity to *1 and monitor the lead groups. Start on-line printing with 50 speed and measure the signal amplitude on the printout.

a. In case of DC= +320 mV

The signal's amplitude on the examined lead must be 20 mm +/- 3 %.

P1	P2	Examined lead
L	all other	I
R	all other	II
F	all other	III
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

b. In case of DC= -320 mV

The signal's amplitude on the examined lead must be 20 mm +/- 3 %.

P1	P2	Examined lead
L	all other	I
R	all other	II
F	all other	III
V1	all other	V1
V2	all other	V2
V3	all other	V3
V4	all other	V4
V5	all other	V5
V6	all other	V6

7.1.4 Latch-up watch check

Only connect the DC generator to the amplifier input according to the table. The DC level has to be controlled between 0 and 450 mV. The filter must be turned off.

Connect the patient cable according to the following table and start the channels one-by-one with the channel selector. On the display check the measurement order quality, the baseline, which can be reset after DC controlling with the blocking command.

During the examination the device indicates the latch-up watch circuit's operation with text message. During the measurement enter the DC values into the table where the text appeared. The comparison levels must be min. 340 mV, max 450mV.

P1	P2	Examined lead	Positive DC (mV)	Negative DC (mV)
L	all other	I		
R	all other	II		
V1	all other	V1		
V2	all other	V2		
V3	all other	V3		
V4	all other	V4		
V5	all other	V5		
V6	all other	V6		

7.1.5 Measuring noise on the input and baseline checking

Make a 10 seconds long recording with the shorted inputs at *2 sensitivity, 25 mm/sec speed from all groups. The filter must be off. Short the device input. Measure the noise and absolute deviation from the baseline on the null-line.

The noise on the input is acceptable if the value of the noise peak-to-peak is not greater than $(0.4 \text{ mm} + 1 \text{ pixel}) = 0.525 \text{ mm}$ on any lead. The null-line is acceptable if the deviation from the baseline is less than 2 mm anywhere on the printout and on the display.

7.1.6 Checking time-constant

Apply 4 mVpp 0.05 Hz sine signal onto the amplifier's input from a ground independent generator according to the table. Set amplifier sensitivity to *1/2. Start on-line recording with 5 mm/sec speed and measure the time-constant on the printout. The time-constant must be min. 3.2 seconds.

P1	P2	Examined lead	Measured time-constant
L	all other	I	
R	all other	II	
F	all other	III	
V1	all other	V1	
V2	all other	V2	
V3	all other	V3	
V4	all other	V4	
V5	all other	V5	
V6	all other	V6	

7.1.7 Checking frequency transfer

Apply +DC signal onto the amplifier's input (2000 +/-0.5% μVpp / 150 Hz sine) from a ground independent generator according to the table. DC must be +320, -320 mV.

The filter must be off.

Connect the patient cable according to the following tables and with the channel selector start the channels one-by-one, and measure the signal amplitude or during 50 mm/sec *1 printing.

a/ In case of DC = -320 mV

The signal's amplitude on the examined lead must be min. 1400 μV .

P1	P2	Examined lead	Measured amplitude
L	all other	I	
R	all other	II	
V1	all other	V1	
V2	all other	V2	
V3	all other	V3	
V4	all other	V4	
V5	all other	V5	
V6	all other	V6	

b. In case of DC = -320 mV

The signal's amplitude on the examined lead must be min. 1400 μ V.

P1	P2	Examined lead	Measured amplitude
L	all other	I	
R	all other	II	
V1	all other	V1	
V2	all other	V2	
V3	all other	V3	
V4	all other	V4	
V5	all other	V5	
V6	all other	V6	

7.1.8 Checking filter**a. "Line" filter on at 50Hz**

Apply 4 mVpp 50Hz sine signal from the generator between the device's V2 and all other connected inputs. The filter is acceptable if the dampening is less than 20dB when the frequency is changed in the 48.5 Hz - 51.5 Hz range. The measurement should be performed on the V2 lead by making a recording at 50 mm/sec speed and normal amplification with the filter on. The recorded signal must be less than 4 mm.

b. "Line" filter on at 60 Hz

Apply 4 mVpp 60Hz sine signal from the generator between the device's V2 and all other connected inputs. The filter is acceptable if the dampening is greater than 20dB when the frequency is changed in the 59 Hz - 61 Hz range. The measurement should be performed on the V2 lead by making a recording at 50 mm/sec speed and normal amplification with the filter on. The recorded signal must be less than 4 mm.

c. "Noise" filter on

Apply 4 mVpp 35Hz sine signal from the generator between the device's V2 and all other connected inputs. The filter is acceptable if the dampening is greater than 20dB. The measurement should be performed on the V2 lead by making a recording at 50 mm/sec speed and normal amplification with the filter on. The recorded signal must be less than 27 mm.

7.1.9 Checking CMRR

a. Checked with 50Hz signal

Connect the patient cable to the M13 measurement device, to which input apply 20 Veff 50Hz sine signal. Amplification *1. Start AUTO recording and check the signal size on the paper. Acceptable if the signal is not greater than 5.6 mm.

b. Checked with 60Hz signal

Connect the patient cable to the M13 measurement device, to which input apply 20 Veff 50Hz sine signal. Amplification *1. Start AUTO recording and check the signal size on the paper. Acceptable if the signal is not greater than 5.6 mm.

7.1.10 Printing ECG signal

Set PACE MAL operating mode on the Phantom 320 generator and make approximately 10 seconds long printouts from all groups at 25 mm/sec speed and *1 amplification. Check the printout quality. The curve must be continuous and clearly visible.

The recording must be repeated in normal heart rate 60 position by connecting the pace generator, set to 700mV/2ms, in series with the R lead.

Make 6 seconds long recording in automatic operating mode.

7.1.11 Checking PC connection

Connect an ECG signal generator to the device input. Monitor the signal on the PC and switch over all the amplification levels, the filter, and all the leads. Check that the setting on the PC and the signal match those on the device. Then start automatic storage on the PC, store the recording, then retrieve it from the database and check the signal quality.

Check the R-wave amplitudes on all leads on the display. Print the signal from the PC on a laser printer through the serial line and check the ECG signal there as well. Check the analysis parameters; compare the numeric values on the display with the amplitude and time parameters from the recording.

7.1.12 Measuring power consumption

In different operating modes, with the voltages in the following table, measure the device power consumption from the mains and the charging adapter.

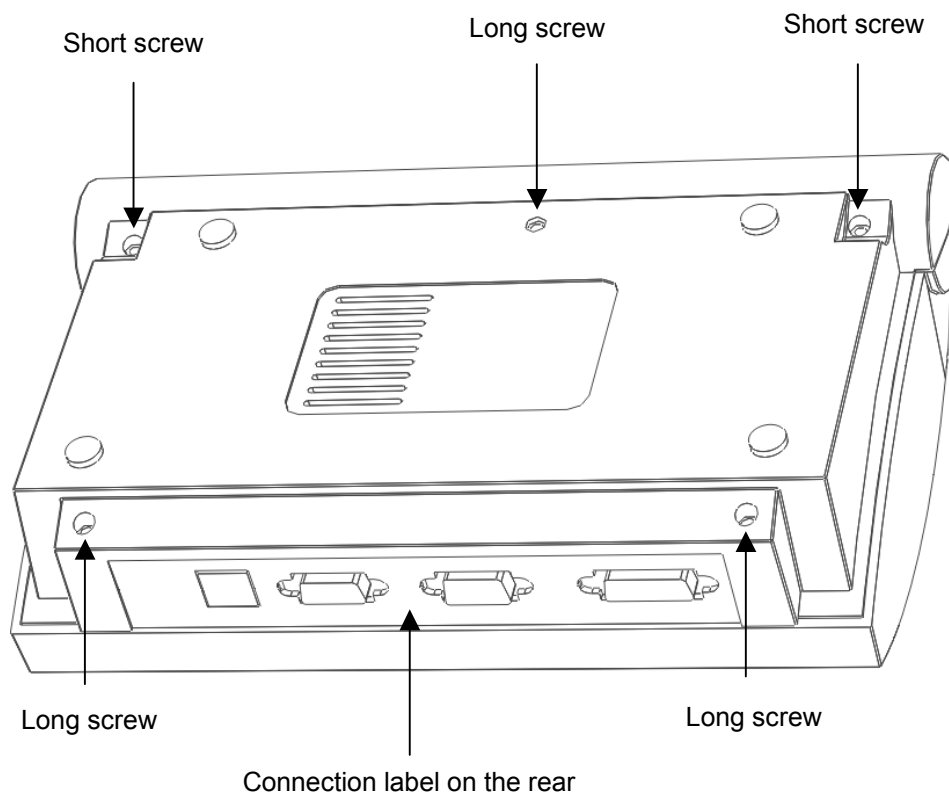
Measurement place	Device off, battery charging	
	max. current	measured current
253 Veff mains voltage	0.1 A	
15 V from charger input (in case of 253 Veff mains)	0.27 A	

8 Maintenance and service procedures

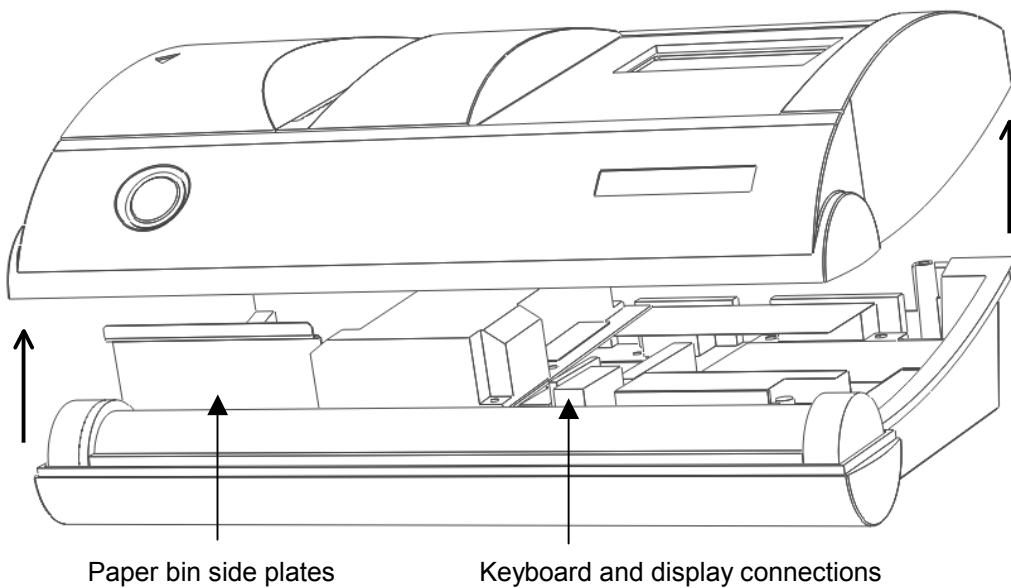
8.1 Device disassembly / re-assembly

The device has to be disassembled in the following order (re-assembly must be performed in reverse order):

1. Remove the paper bin cover.
2. Remove the self-adhesive connection-label from the back (make sure that the label is not damaged, as it can be replaced after re-assembly).
3. Turn the device upside-down and remove the five screws (during re-assembly take care to note the different length screws).

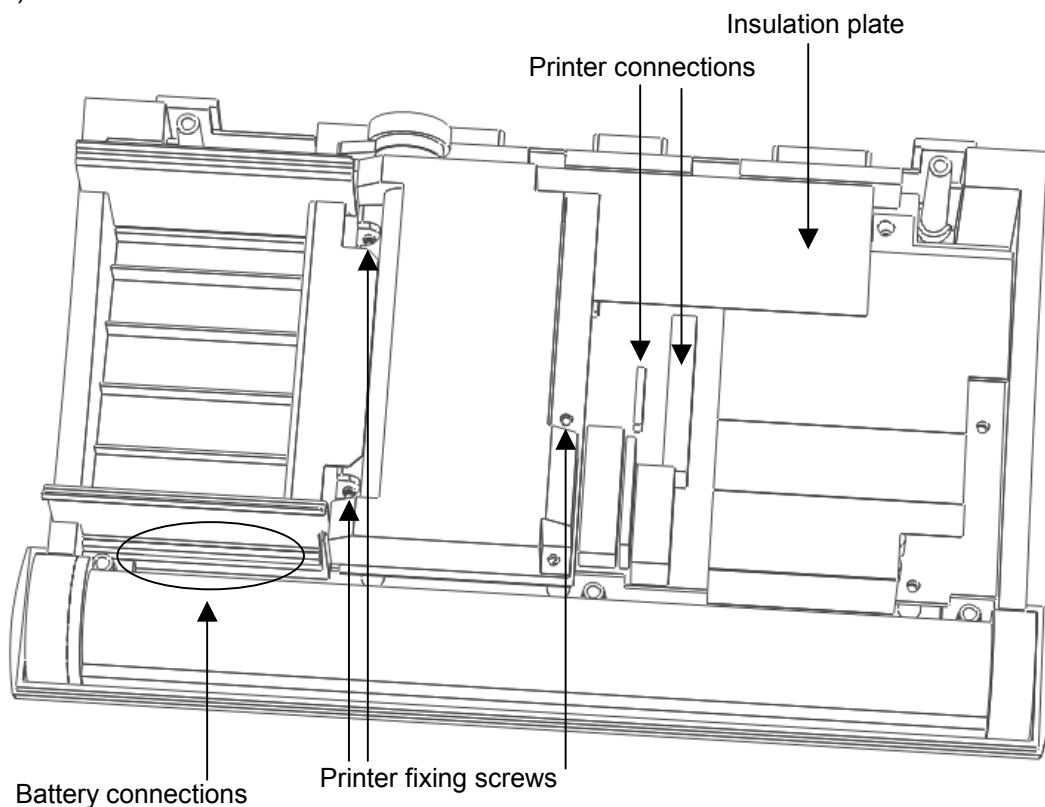


4. Turn the device right side up again, and carefully lift the device top (during re-assembly take care that the paper bin side plates fit into the correct places in the top part).
5. Disconnect the keyboard and display cards.
6. Lift the top part.

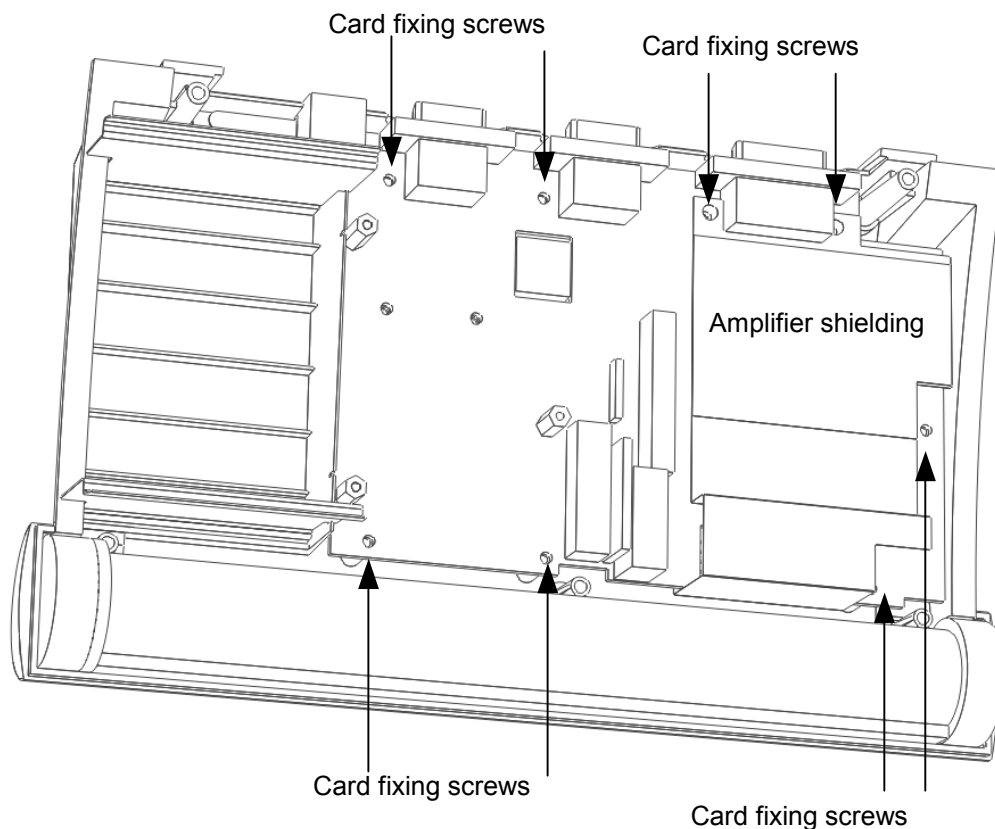


8.1.1 Further disassembly of the bottom part:

1. Remove the battery connections.
2. If this was the goal of disassembly, remove the battery.
3. Remove the paper head connections.
4. Remove the printer head mechanics after removing the three indicated screws.
5. Remove the insulation plate glued to the connections (during re-assembly these must be glued back).

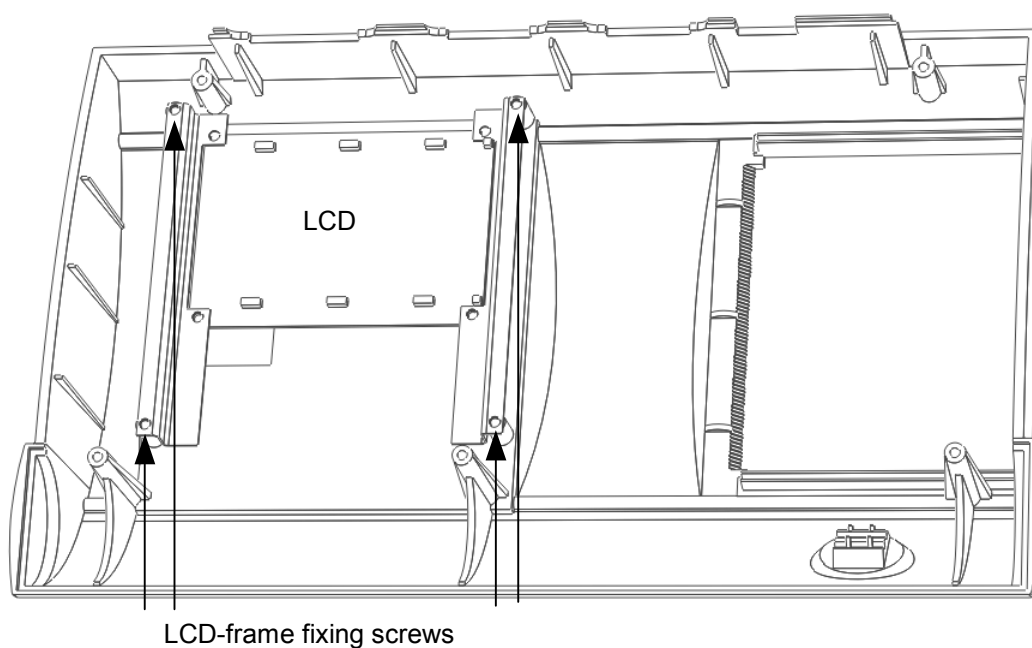


6. After removing the indicated screws, the HS80G110 card can be removed.
7. Before removing the amplifier part shielding, unsolder the connecting cables.
8. The shielding is glued from the bottom, should be glued back during re-assembly.

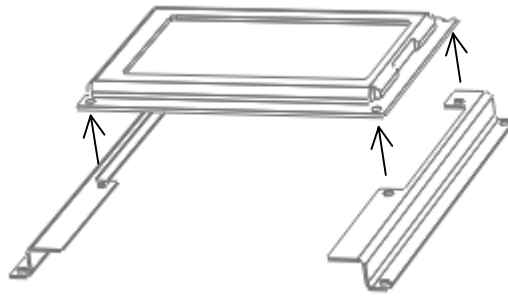


8.1.2 Further disassembly of the top part:

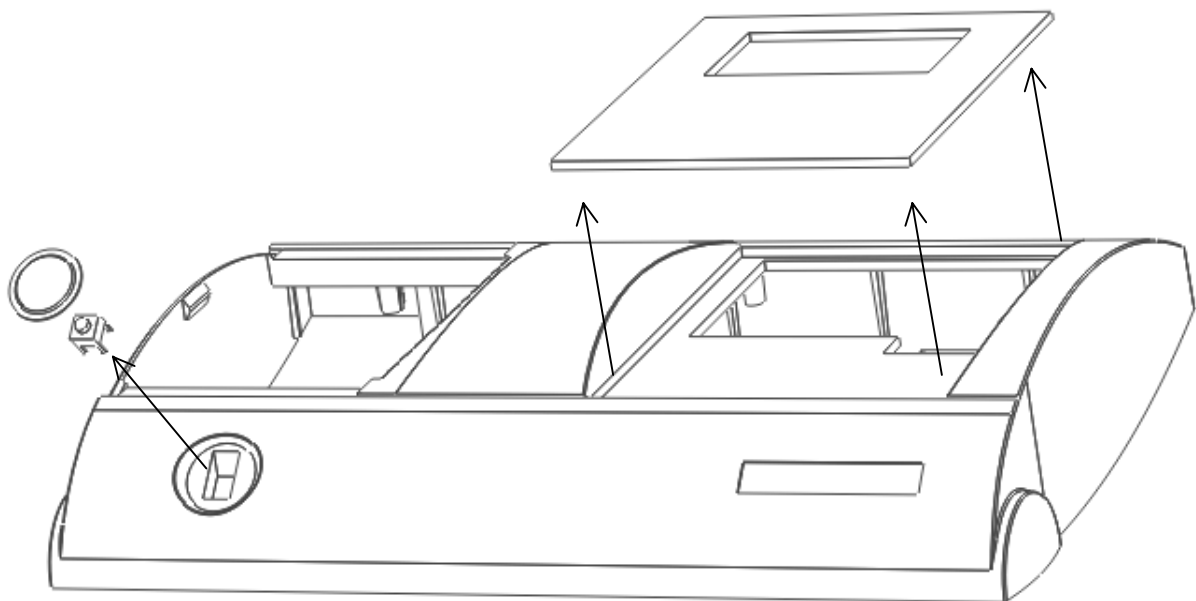
1. Remove the LCD-frame holding screws and remove the LCD (during re-assembly note the LCD position: tilt, etc).
(During re-assembly the original cable positions must be used).



2. Remove the frame from the LCD by unscrewing the four fixing screws.



3. Before unsoldering the ribbon-cable, remove the soldering insulating and fixing glue (when installing the ribbon-cable the soldering points should be insulated and fixed (for example with heat-melting glue)).
4. After removing the LCD, the keyboard can be pushed out from the device's top part.
5. After removing or replacing the keyboard, the cable soldered onto the power switch has to be removed. To do this:
 - a. Remove the soldering insulating and fixing glue from the power switch.
 - b. Unsolder the cables.



8.2 Reprogramming the device

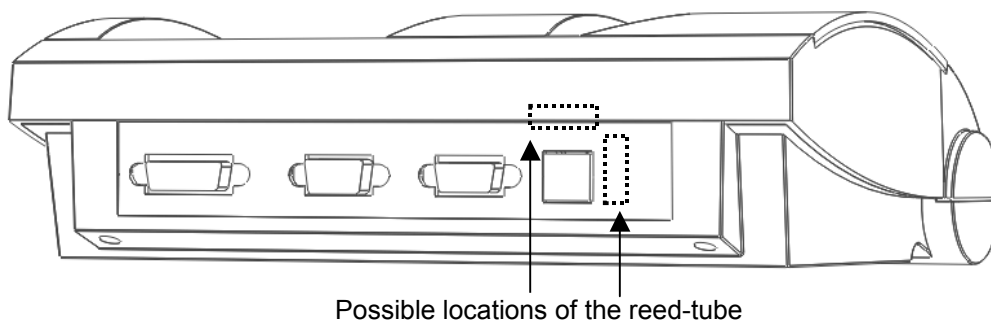
Beside the device, the following are required to reprogram the device:

1. The charging adapter included with the device
2. Serial cable
3. PC
4. Magnet for reprogramming
5. The software update program

The reprogramming procedure

1. Connect the charging adapter to the device.
2. Connect to the PC with the serial cable.
3. Find the magnet's proper position:

The magnet is required to operate the reed-tube at the backside of the device above/next to the charging adapter. Closing the sensors in this places the device into the programming mode (the magnet can be anything magnetic, for example something that magnetizes a screwdriver).



How to find it:

- 3.1. The device is turned off; the charging adapter and the serial cable are connected.
- 3.2. Place the magnet tight against the device's back, next to the charging adapter connection and turn the device on.
If the reed-tube switched, nothing is visible on the display after it has been turned on. The device is in programming mode. Remove the magnet and turning the device off and on again starts the device in normal mode.
- 3.3. If the tube did not switch, try different positions, moving the magnet polarity around the charging adapter connection.
- 3.4. After several unsuccessful tries read the Troubleshooting section of the manual.
4. With the device turned on and the magnet in place, start the PC-based download program and follow the instructions (magnet placement / removal, device on / off, etc).
5. In case of incorrect download, repeat the process.
6. After several unsuccessful tries, read the Troubleshooting section of the manual.

9 *Circuit diagrams*

9.1 *Main board*

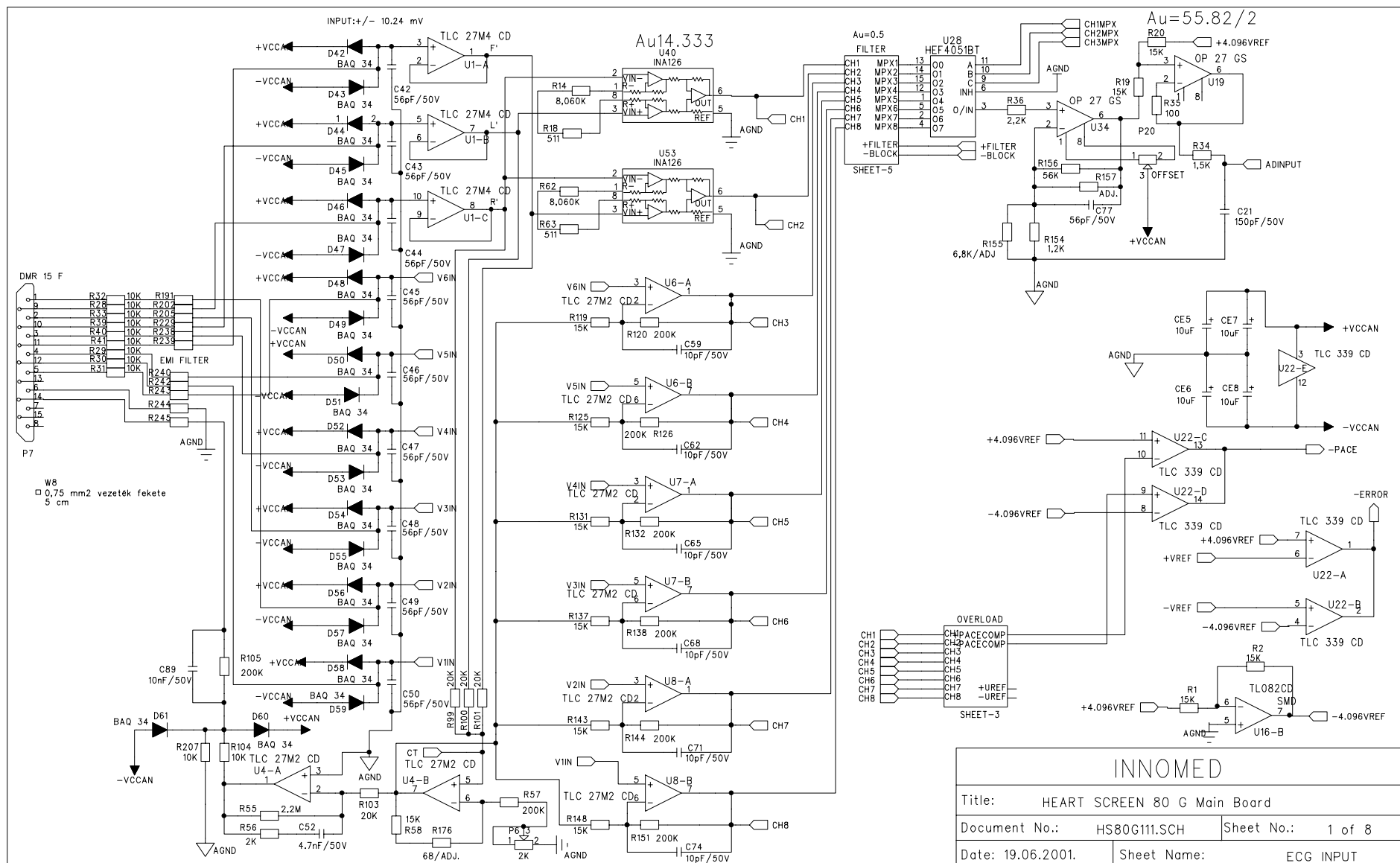
HS80G110.sch

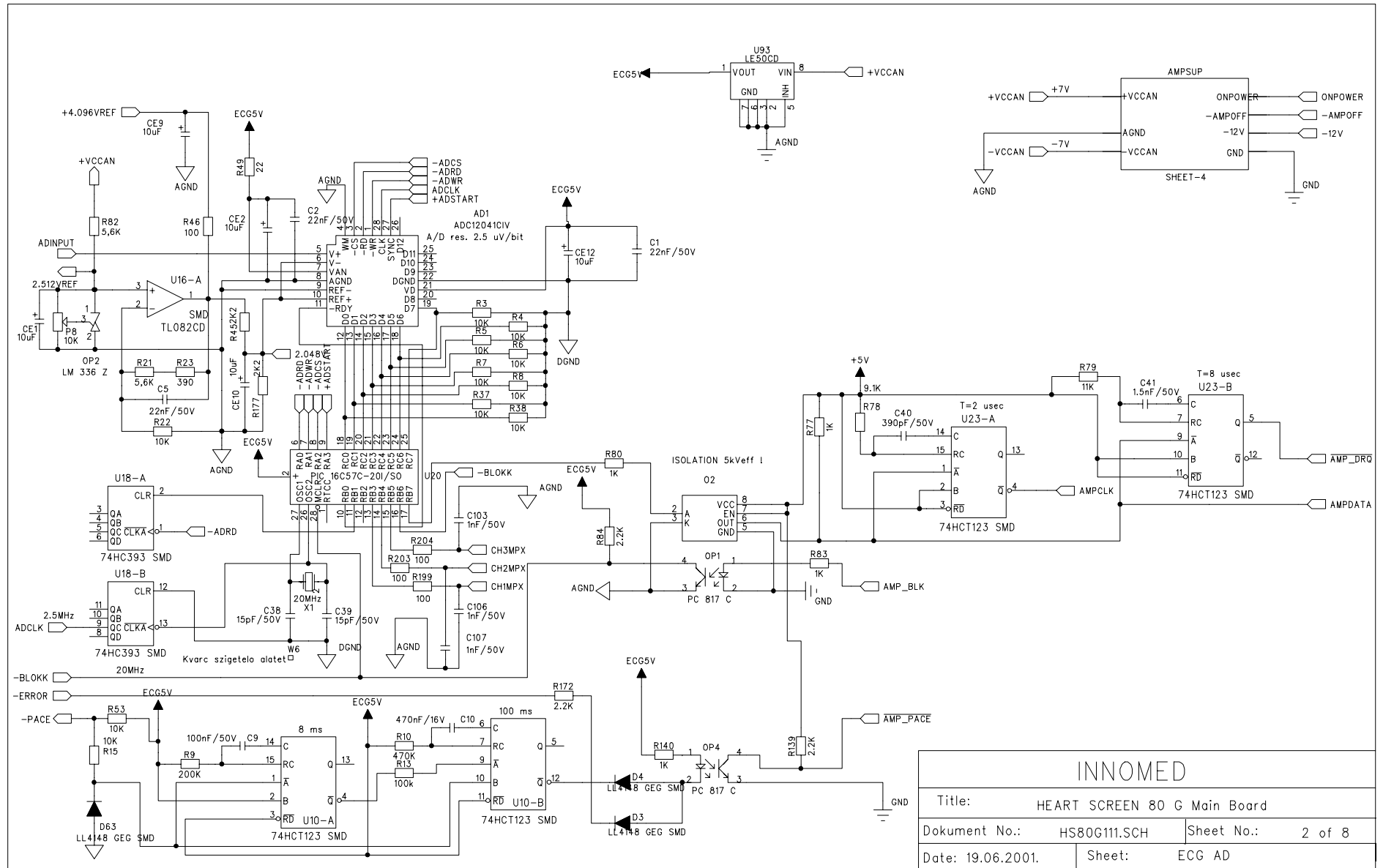
9.2 *Keyboard and LCD*

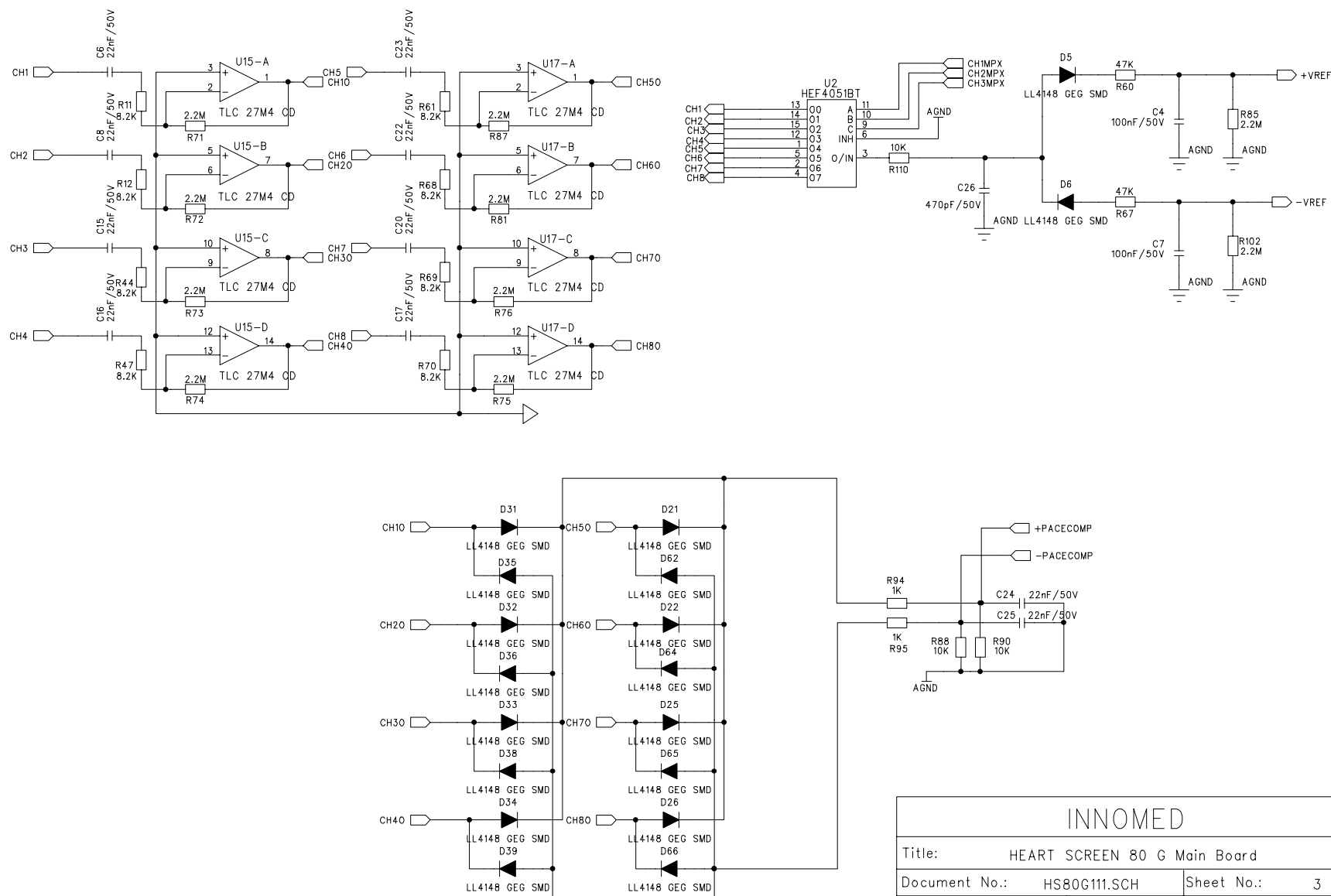
HSGKB100.sch

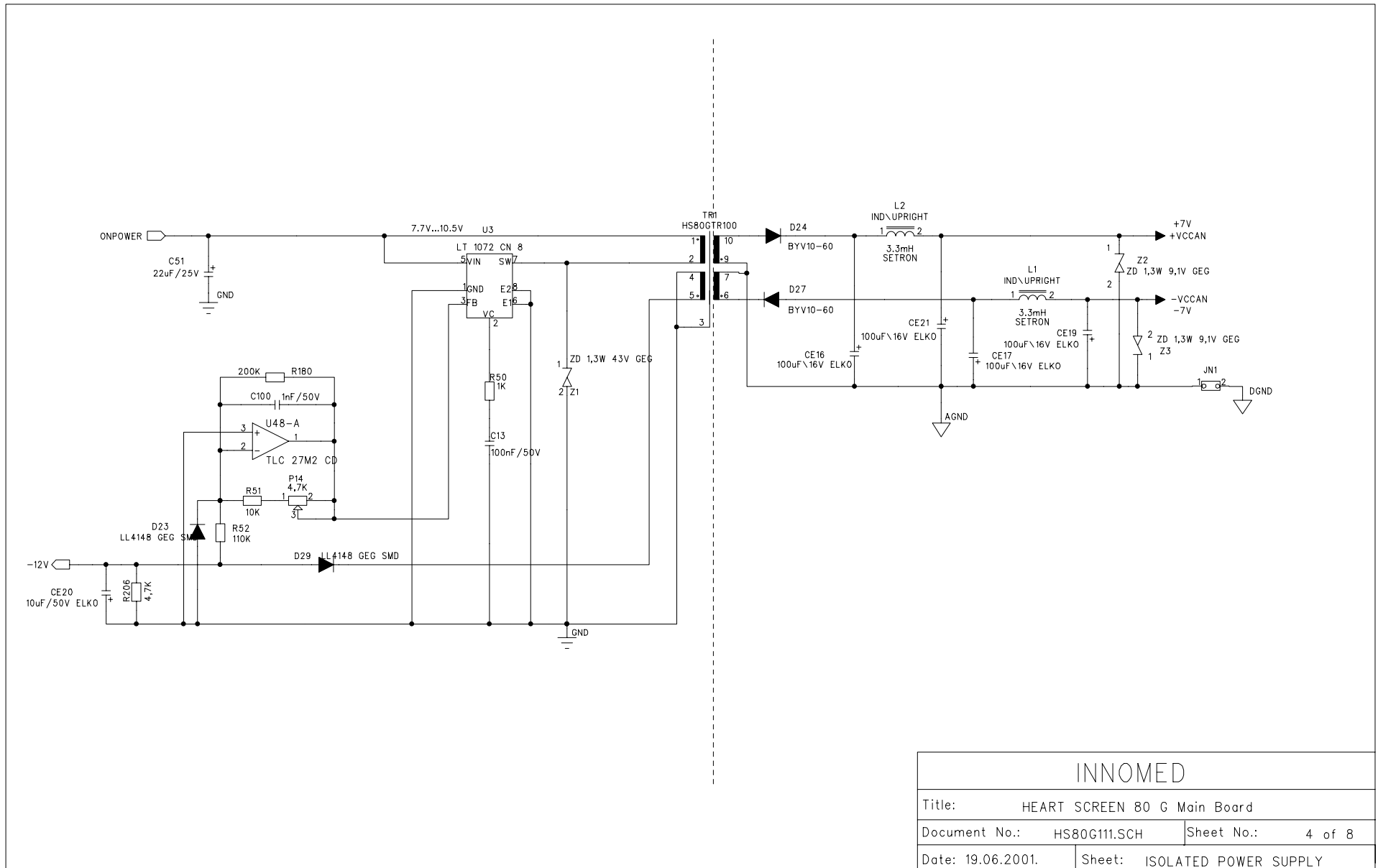
9.3 *Accu pack*

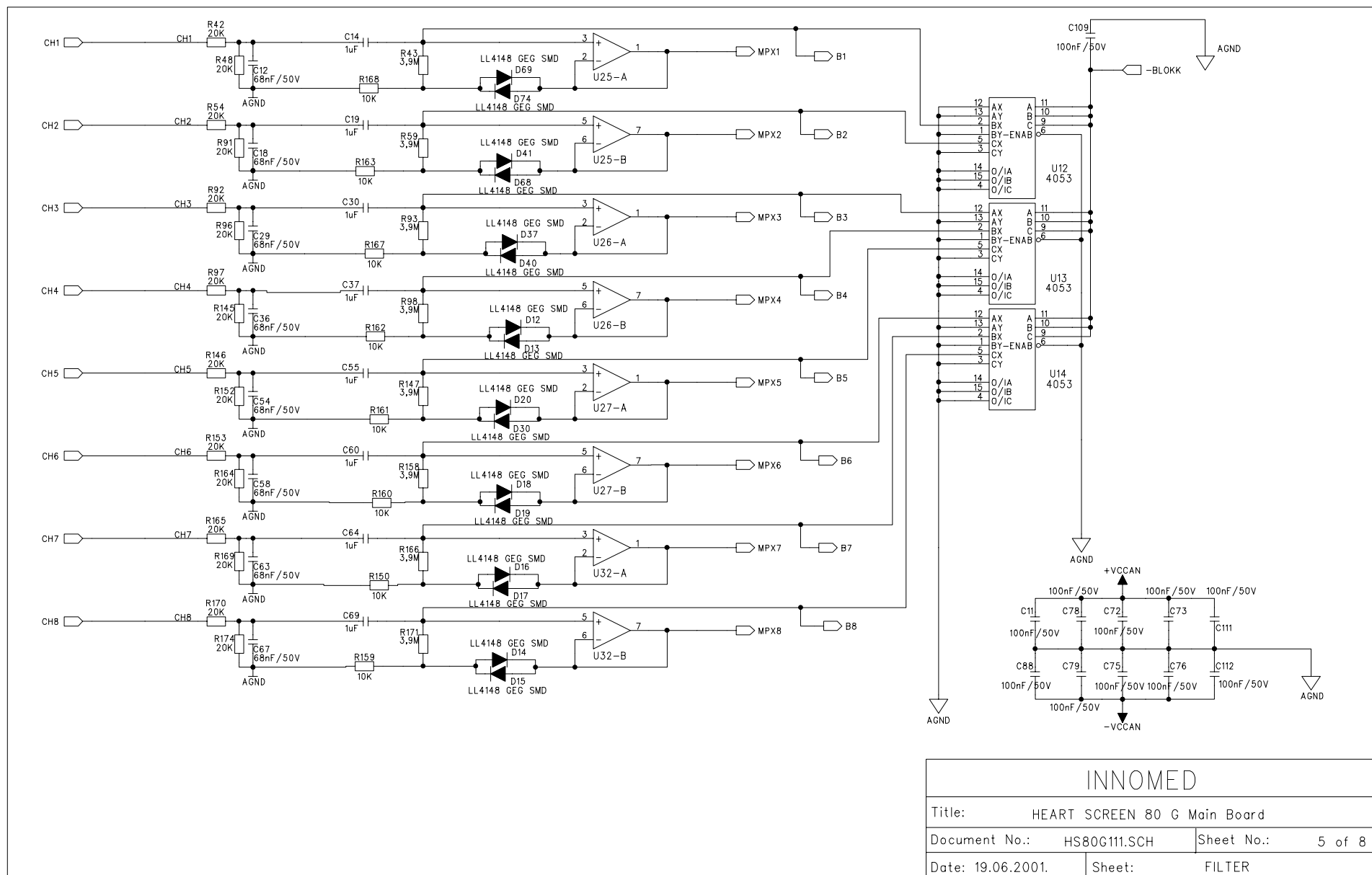
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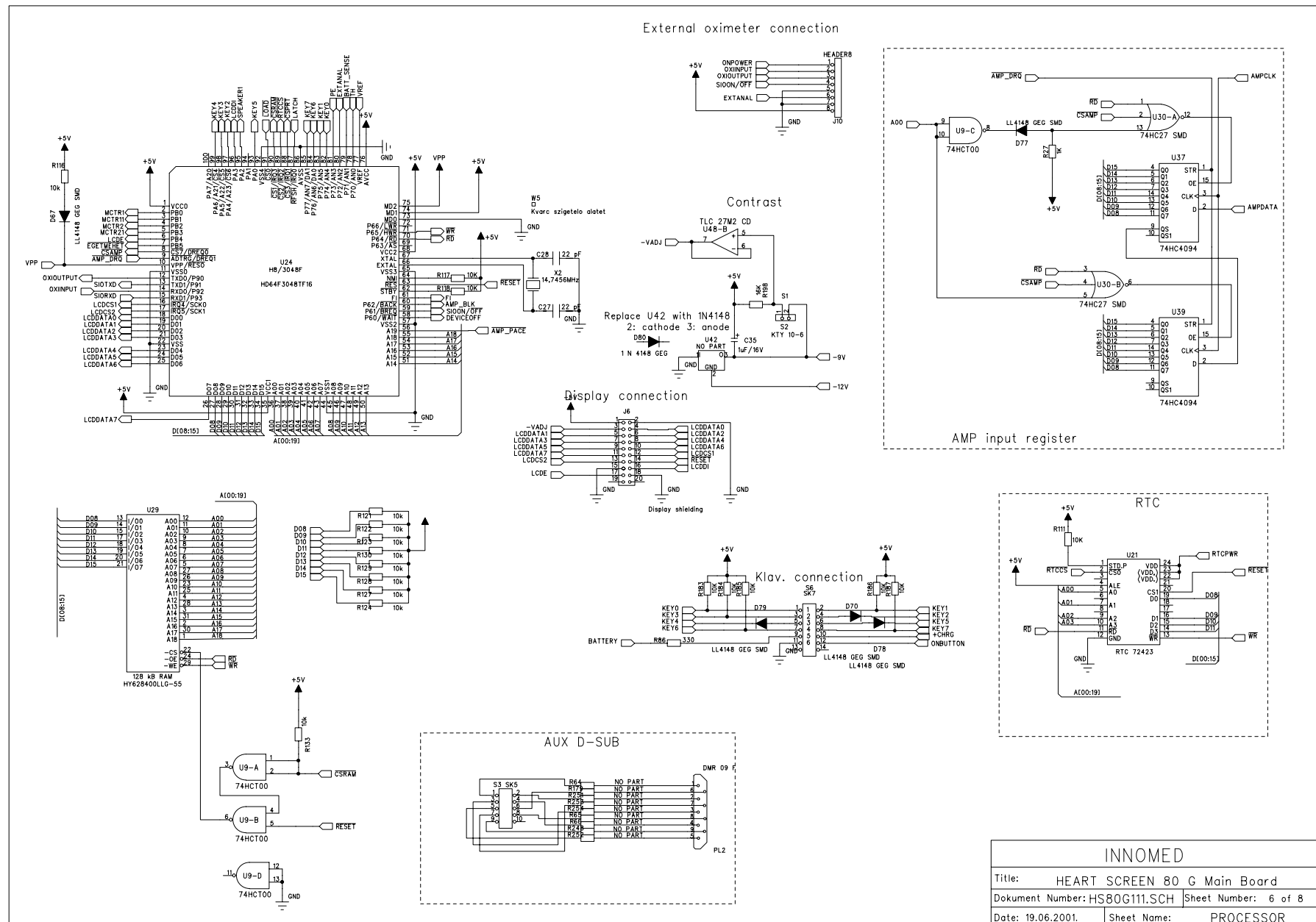


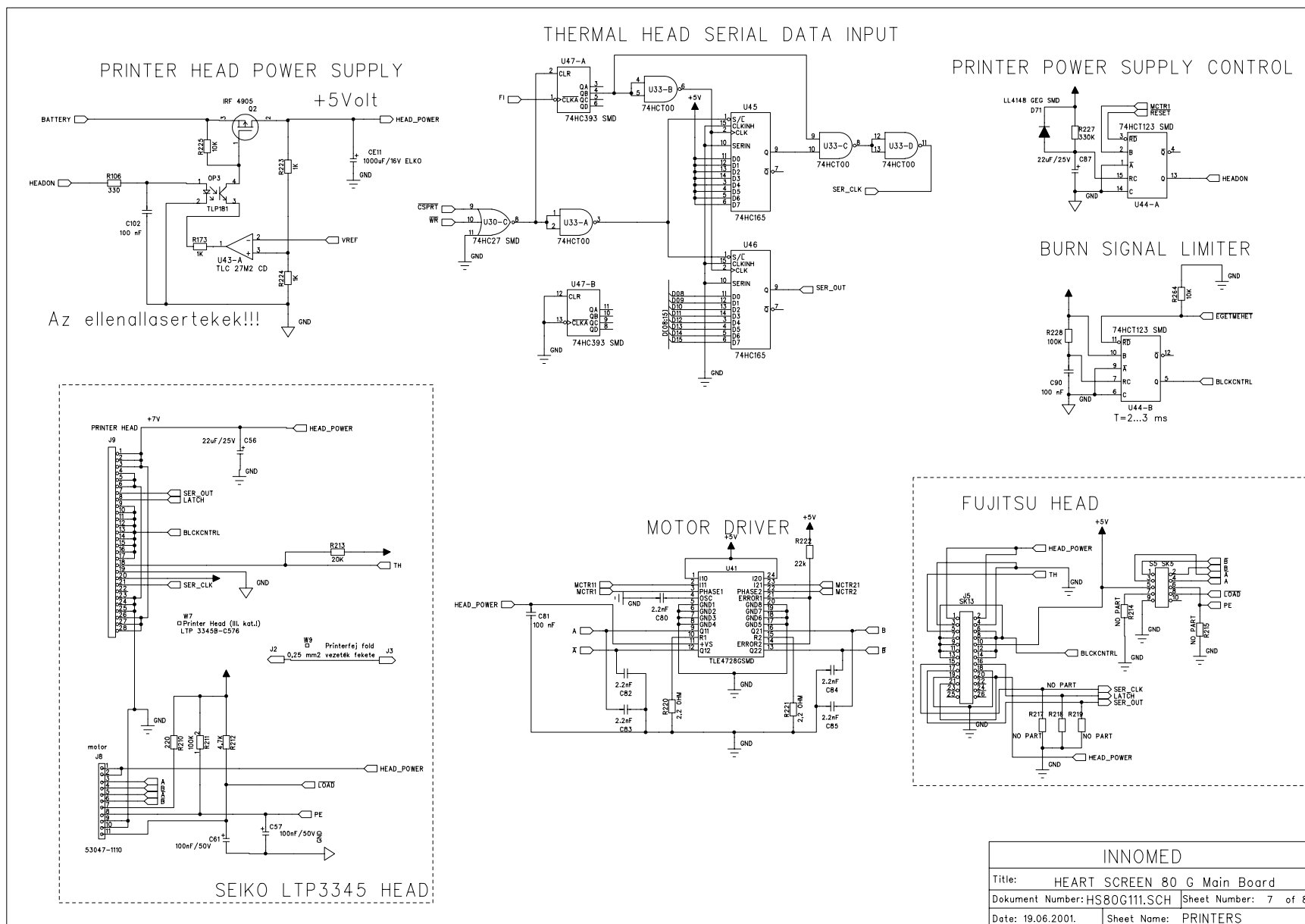


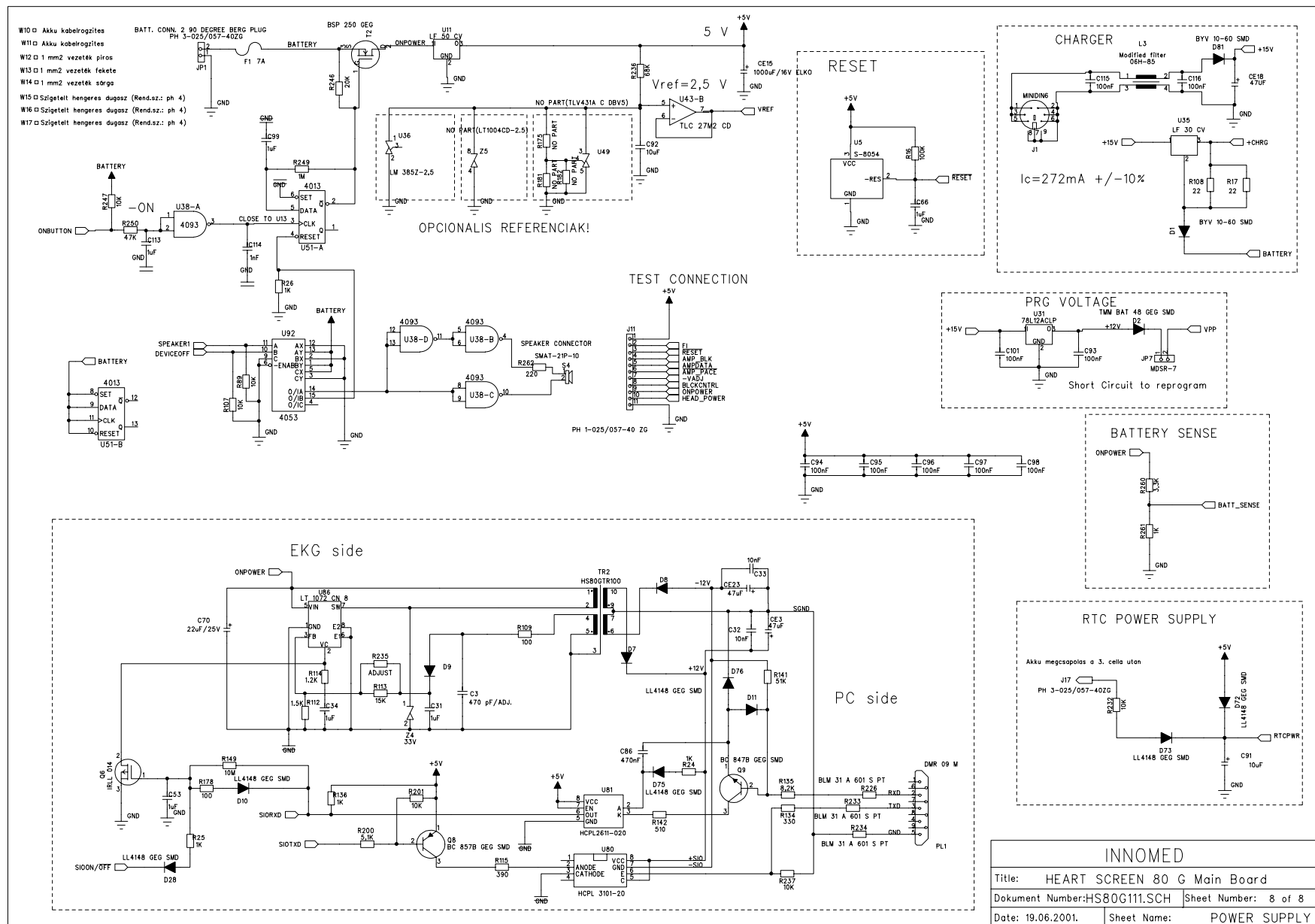


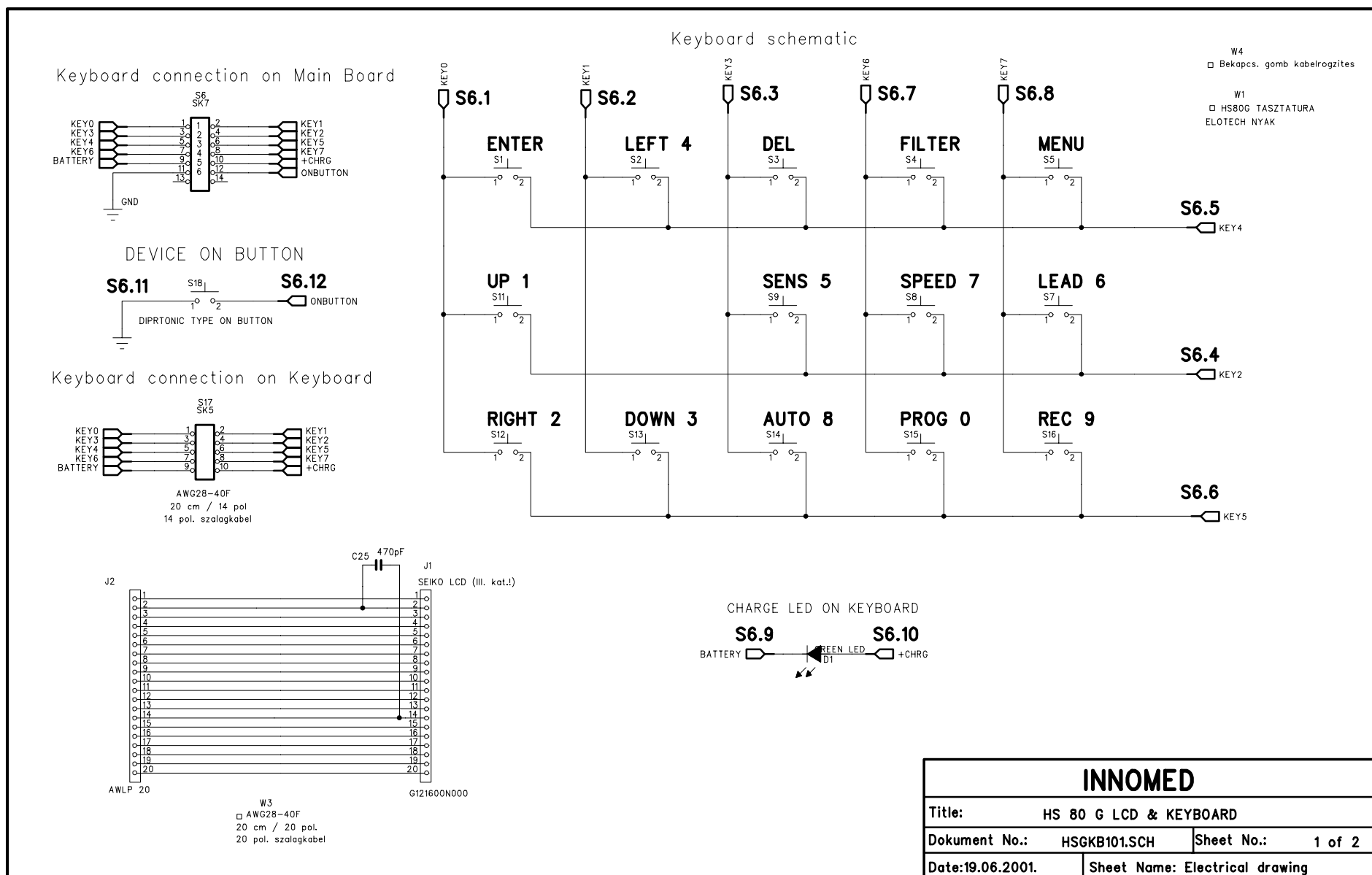


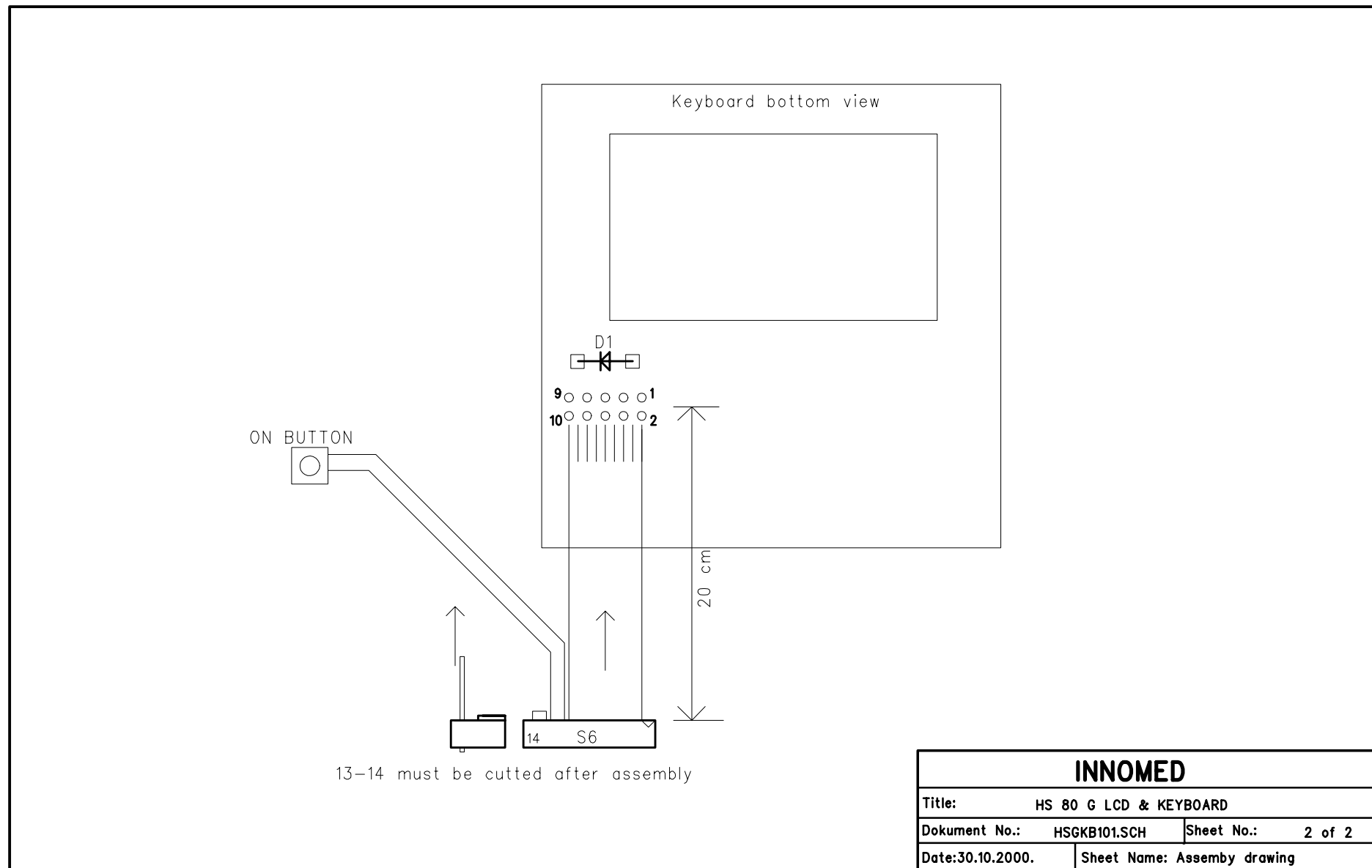


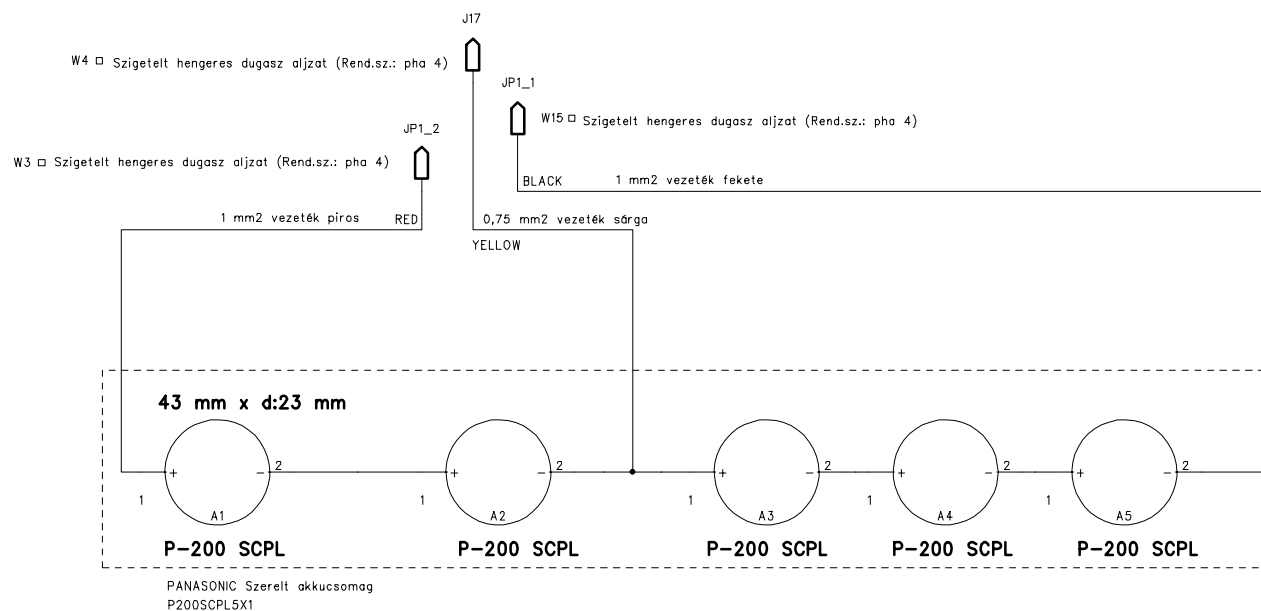




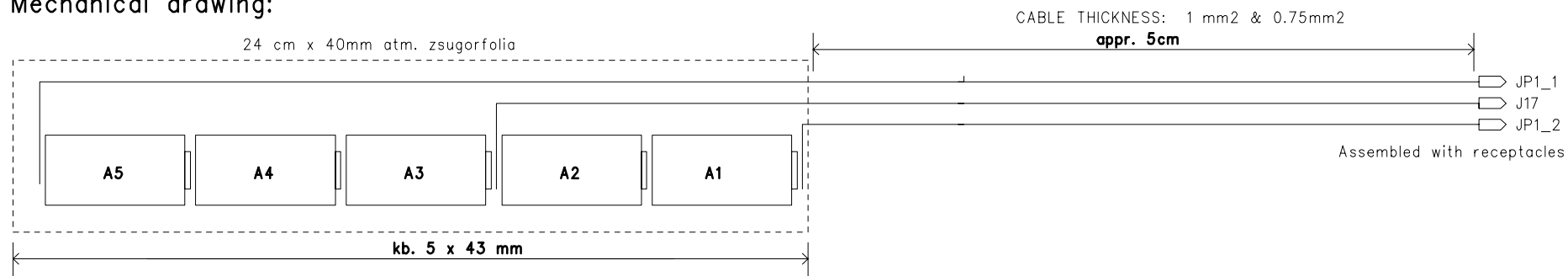








Mechanical drawing:



INNOMED		
Title: HSG0G ACCU.PACKAGE		
Doc. No.: HSGAC101	Sheet No.: 1 of 1	
Date: 19.06.2001.	Sheet Name:	

10 *Assembly drawings*

