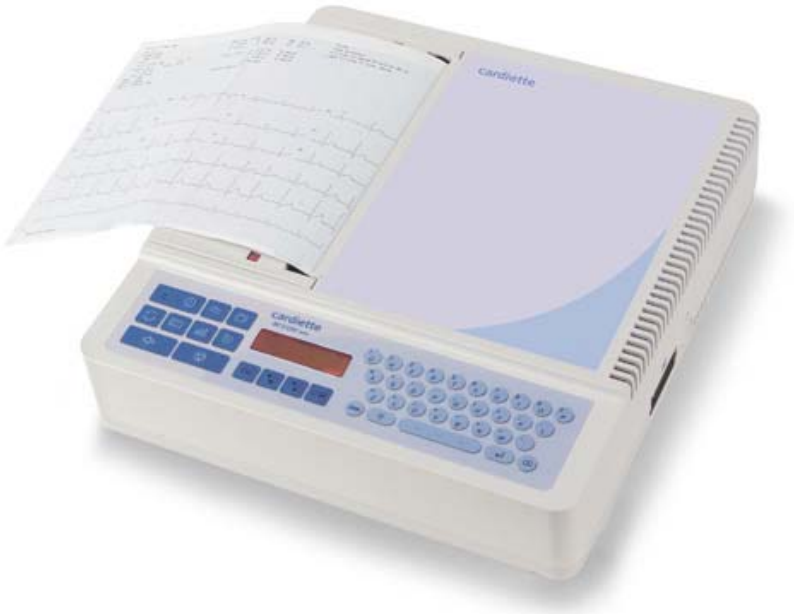
cardiette



ar2100 adv

service manual

CE 0470

english

This Service Manual has been prepared with the objective of giving the user all the information necessary to obtain the best use of the **cardiette® ar2100 adv**.

General information

et medical devices SpA, continuously in search of technological improvement and customer satisfaction, reserves the right to modify this publication without prior notice at any time.

Contents

1 Introduction

ar2100 adv epitomises the reliability, modularity, versatility and capacity to be updated which characterise the latest generation of **cardiette**®electrocardiographs.

ar2100 adv is a portable electrocardiograph with dual power supply, (mains and rechargeable internal batteries), which in the basic configuration will:

- ✓ -record an ECG exam in automatic or manual mode;
- ✓ reproduce the ECG signal on 210 mm paper in 3-6 12 channel format thanks to the high resolution thermal printer;
- ✓ storage of the most recent recording in automatic mode and print additional copies.

*In just a few minutes, your **ar2100 adv** can be equipped with:

- ✓ "memory option": to store up to 40 full ECG exams, with no need to print out immediately on paper ("paper saving" mode);
- ✓ "ECG measurements option": automatic ECG parameter measurement program;
- ✓ "ECG signal interpretive option": a useful and dependable diagnostics support provided by the "HES" program;
- ✓ "arrhythmia option": program enabling detection of arrhythmia events during continuous recording;
- ✓ "HRV analysis option": program enabling detection of variations in heart rate;
- ✓ "L.E.M.S - PC archive option": to store the exam to archive on a Personal Computer running "L.E.M.S." (Local ECG Management System) software;
- ✓ "R.T.E. - PC-ECG option": for real time display of the twelve leads on your computer screen to allow management of patient medical records and archiving of exams in digital format using " R.T.E" (Real Time ECG) software. R.T.E has an optional "HES" module for automatic interpretation of the ECG signal.

* By updating the firmware. Contact your distributor for further details.

1.1 Particular recommendations and warnings

- ✓ This service manual is for the use of competent technical staff only.
- ✓ Always use the equipment according to the instructions in this manual.
- ✓ The device is equipped with a set of standard accessories. For reasons of safety, reliability and conformity with the Medical Devices Directive 93/42/EEC, use only original accessories or accessories approved by the manufacturer.
- ✓ The device is equipped with a special long-life thermal head writing system, which allows maximum writing precision. To avoid frequent and costly replacements and repairs, always use the original paper or paper approved by the manufacturer. The manufacturer will not accept liability for any damage to the device or any other adverse effect caused by the use of unsuitable paper.
- ✓ Do not subject the device to impact or excessive vibrations.
- ✓ Do not allow liquids to penetrate inside the device. If this should accidentally occur, have the device tested by an Authorized Assistance Centre to verify its functional efficiency, before using it again.
- ✓ Make sure that the value of the supply voltage corresponds to that indicated on the data plate of the device.
- ✓ If you are using the device in connection with others, ensure that: all connections are made by skilled persons; all connections comply with safety regulations; all other devices connected respond likewise to regulations. Non-compliance with these regulations can cause physical harm to the patient connected and to the person operating the device. Should it be difficult to obtain the necessary information for assessing the risk of the individual connections, apply directly to the manufacturers concerned or avoid making the connections.
- ✓ In the event of other equipment being connected directly or indirectly to the patient, check for the possible risks caused by the sum of the leakage currents on the body of the patient.
- ✓ The device is protected against defibrillation discharges in accordance with IEC standard 601-1-25; to ensure that the signal is restored, use only original electrodes or electrodes responding to IEC and AAMI standards.
- ✓ If an electrosurgical scalpel is in use, the patient cable should be disconnected from the device.
- ✓ In any event, the greatest care should be taken when using defibrillators or high-frequency surgical devices at the same time as the ECG. If you have any doubts while using such devices, disconnect the patient from the electrocardiograph temporarily.
- ✓ The device recognizes the impulses generated by a pacemaker and does not interfere with its operation, as prescribed by standards in use at the time of drafting this manual.
- ✓ Avoid exposing the equipment to extreme temperatures, excessive dust or dirt, and very salty or damp environments; observe the ambient conditions described in detail under the "*Technical specifications*" heading.
- ✓ Periodically check the efficiency of all accessories and of the device itself. Use the built in test function to perform an initial efficiency check. Contact the Authorized Assistance Centre whenever the device seems to be operating irregularly.
- ✓ To prolong the life of your ar2100adv, have it periodically checked at an Authorised Assistance Centre
- ✓ **Warning:** do not use the device in the presence of anaesthetics or volatile gases!
- ✓ **Warning**: the indications obtained using automatic interpreting programs or other diagnostic aids must be reviewed and countersigned by a qualified medical person!
- ✓ **Warning**: the device is provided with an IR interface for the transfer of data to other devices. The IR interface must not be masked , even accidentally, as this will adversely affect its capability and its operation, interrupting and preventing the correct flow of data.
- ✓ **Warning:** *Environmental protection:* When no longer in use the device must be disposed of according to local regulation, do not dispose as ordinary refuse.
- ✓ The manufacturer will acknowledge liability for the safety, reliability and functional efficiency of the device only if:
  - modifications and repairs are performed by the manufacturer or by an Authorized Assistance Centre;
  - the a.c. mains power supply of the premises in which the device is used corresponds to current regulations;
  - the device is operated according to user instructions;
  - any accessories in use are those approved by the manufacturer.

2 Description of the device

The device consists of the following basic elements:

2.1 Mother board

This is a "Fine line" multilayer printed circuit board for mounting SMD components.

It houses most of the electronic circuits of the device.

2.2 Battery

Lead battery.

2.3 Keyboard card

The keyboard card consists of the device functional keys and LED/display messaging devices.

2.4 Printer unit

This consists of the thermal printer head support and the mechanical elements required to position it correctly.

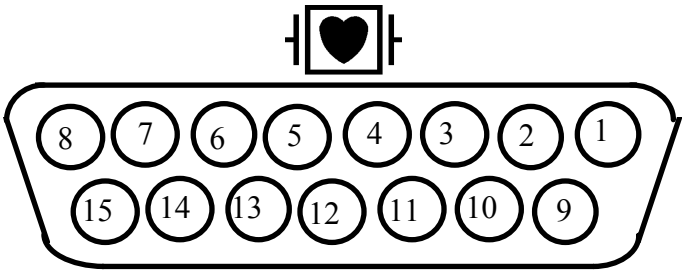
2.5 IR Module (RS232)

The function of the IR module is to transmit and receive data from an external PC.

3 Inputs and outputs

Direct connections from the **ar2100 adv** to external equipment may only be made using the IR serial port, not by cable.

3.1 Connection to the patient input port



Port from connection side

Pin	1 =	IN	C2	(electrode C2)
Pin	2 =	IN	C3	(electrode C3)
Pin	3 =	IN	C4	(electrode C4)
Pin	4 =	IN	C5	(electrode C5)
Pin	5 =	IN	C6	(electrode C6)
Pin	6 =	AGND		(analogue ground)
Pin	7 =	NC		
Pin	8 =	DGND		(digital ground)
Pin	9 =	IN	R	(electrode R)
Pin	10 =	IN	L	(electrode L)
Pin	11 =	IN	F	(electrode F)
Pin	12 =	IN	C1	(electrode C1)
Pin	13 =	NC		(non connected)
Pin	14 =	IN	N	(electrode N)
Pin	15 =	NC		(non connected)

4 Testing the safety characteristics

The safety regulations envisage two important tests:

- ✓ *The leakage currents test* measures the value of the currents lost in relation to the safety of the patient and the operator.

Warning: *All safety tests must be performed according to standards EN.60601-1(1990 paragraphs 19 - 20) EN 60601-2-25 (1995) unless otherwise specified in the local safety regulations.*

4.1 Leakage currents test

Warning: *This test must be performed every time the device has been opened for inspection and/or repair, and in any event every two years, unless otherwise specified by the local safety regulations.*

Connect the electrocardiogram to the battery charger, and then connect this assembly to the measuring instrument according to the instrument's manual, recalling that:

1) *The leakage current to the casing* is measuring between the mains supply circuits and a metal sheet no greater than 20 x 10 cm pressed against the casing of the device.
2) *The leakage current in the patient* is measured between the mains and the applied part. For connection to the applied part use the patient lead itself.
3) *The leakage current in the patient with mains voltage directly on the applied part* (first failure condition) is measured between the meta sheet connected to the device and the applied part.
4) *The auxiliary current in the patient* is measured singly on each electrode (excluding the reference electrode) compared to all the other electrodes connected together.

Note: *Make the measurements following the indications in the instrument user manual, and check that the leakage current values measured are less than or equal to those listed in table IV.*

Table IV.
Admissible permanent values for leakage and auxiliary currents in the patient in mA (milliamperes).

Current path	CF type	
	N.C.	S.F.C.
Leakage current to earth	0.5	1
Leakage current in case	0.1	0.5
Leakage current in the patient d.c – a.c.	0.01	0.05
Leakage current in the patient (mains voltage in applied part)	-----	0.05
Auxiliary current in patient d.c – a.c.	0.01	0.05
N.C. = Normal condition		
S.F.C. = First failure condition		

5 Testing the main technical characteristics of the electrocardiograph

Warning: *All tests must be performed in compliance with the provisions of the related general, detailed and performance safety regulations listed in the technical characteristics section*

5.1 Instruments necessary:

a) sample mV generator with the following characteristics:

b) low frequency sine wave generator;

c) ECG simulator.

5.2 Sensitivity test

- ✓ set the device up to record 6 channels on leads V1 to V6 with sensitivity of 20 mm/mV;
- ✓ connect the patient cable to the device;
- ✓ connect terminals C1 ÷ C6 of the patient cable connected to the device to the positive pin of instrument 5.1.a);connect all the other cable terminals to the negative pin of instrument 5.1 a);
- ✓ record the signal for a few seconds;
- ✓ check that the amplitude of the recorded signal is 20mm. +/- 5% on all channels.

5.3 Testing the ECG leads

- ✓ switch the device on;
- ✓ connect the patient cable to the device;
- ✓ connect the red termination of the patient cable to the positive pin of the instrument specified in point 5.a.a and the remaining wires to the negative pin.
- ✓ start recording and check that the amplitude in mm of the signal, and its polarity (positive or negative) comply with the values indicated in table 5.3.
- ✓ repeat the measurements in sequence with the remaining active terminations G - V - C1 - C2 - C3 - C4 - C5 - C6 of the patient cable using the method described in c), and check that the values correspond to those indicated in table 5.3.

PATIENT CABLE AND LEADS TEST		
CONNECTIONS FOR THE TEST		
INSTRUMENT		**PATIENT CABLE CONNECTIONS**
Connector	Patient cable terminations	N. 1 Termination to positive apart from black
+ ◎	①	N. 4 Terminations to negative with 5 wire cable
- ◎	② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩	N. 9 Terminations to negative with 10 wire cable
Square wave signal from:		Electrocardiograph: amplification 1mV/10mm
1 Hz ± 1% 1 mVpp ± 3% ⎍		signal recorded in mm ±5%

TABLE OF VALUES

Term. to positive	**LEADS AND VALUE OF IMPULSE**											
	I°	**II°**	**III°**	**aVR**	**aVL**	**aVF**	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**
	mm	**mm**	**mm**	**mm**	**mm**	**mm**	**mm**	**mm**	**mm**	**mm**	**mm**	**mm**
R	- 10	- 10	0	+ 10	- 5	- 5	- 3.3	- 3.3	- 3.3	- 3.3	- 3.3	- 3.3
G	+ 10	0	- 10	- 5	+ 10	- 5	- 3.3	- 3.3	- 3.3	- 3.3	- 3.3	- 3.3
V	0	+ 10	+ 10	- 5	- 5	+ 10	- 3.3	- 3.3	- 3.3	- 3.3	- 3.3	- 3.3
C1	0	0	0	0	0	0	+ 10	0	0	0	0	0
C2	0	0	0	0	0	0	0	+ 10	0	0	0	0
C3	0	0	0	0	0	0	0	0	+ 10	0	0	0
C4	0	0	0	0	0	0	0	0	0	+ 10	0	0
C5	0	0	0	0	0	0	0	0	0	0	+ 10	0
C6	0	0	0	0	0	0	0	0	0	0	0	+ 10

Table 5.3

5.4 Testing the paper feed rate

- ✓ switch on the device and connect the patient cable;
- ✓ connect terminals C1 ÷ C6 of the patient cable to the positive pin of instrument 5.1.a);
- ✓ connect all the other cable terminals to the negative pin of instrument 5.1 a);
- ✓ using the instrument with a square wave of 1 Hz and an amplitude of 1 mVpp;
- ✓ record the signal on leads V1 ÷ V6;
- ✓ measure the length of the wave cycle recorded on the paper.

The results should be as follows:

Period = 50 mm +/- 5% for a feed rate of 50 mm/s;

Period = 25 mm +/- 5% for a feed rate of 25 mm/s;

Period = 5 mm +/-10% for a feed rate of 5 mm/s;

5.5 Frequency response test

- ✓ switch on the device and connect the patient cable;
- ✓ connect terminals C1 ÷ C6 of the patient cable to the positive pin of instrument 5.1.a);
- ✓ connect all the other cable terminals to the negative pin of instrument 5.1 a);
- ✓ set the sine wave generator to 10Hz with an amplitude of c. 1mVpp;
- ✓ select leads V1 ÷ V6 and a sensitivity of 10 mm/mV.;
- ✓ make a recording and adjust the amplitude of the generator so as to obtain a 10 mm excursion of the signal recorded;
- ✓ vary the generator frequency from 0.5Hz to 100Hz with constant amplitude;
- ✓ check that the frequency response is in accordance with the values in table 5.5.

Amplitude of signal in mVpv	**Unfiltered sinusoidal input signal in Hz**	**Relative tolerance of signal 10 Hz – 10 mm**
1	From 0.67 to 40	± 10%
1	From 40 to 100	+ 10% - 30%
0,5	From 100 to 150	+ 10% - 30%

Table 5.5

Note: *The 0.5 Hz pitch linear phase anti-drift filter is always on and cannot be switched off.*

The 50 or 60 Hz filter eliminates modified notch digital type mains disturbances in the linear phase, with a frequency response of 32 Hz - 3dB.

6 Functional blocks

6.1 Mother board

The motherboard is based on the following principal components:

6.1.1 Processor

- ✓ 32 bit Fujitsu MB91101 RISC microprocessor with 12 MHz clock, 2 x 8 Mb flash memories installed.
- ✓ These memories house:
- ✓ *boot code;*
- ✓ *operating system software;*
- ✓ *applications software;*
- ✓ *calibration data;*
- ✓ *ecg archive.*
- ✓ The device also has 2 x 4 Mb static rams.

Testing the mother board circuits

- ✓ Execution of ram self test.

6.1.2 Battery charger

The battery charger section consists of the following parts:

- ✓ Autosense AC mains adapter circuit, 230/115Vac, out 22 Vac, fuse protected, and PTC protection against overheating.
- ✓ Mains filter against electromagnetic disturbances.
- ✓ Rectification, voltage stabilisation and current limitation circuits.

Testing the battery charger circuit (see sheet 9 el diag)

- ✓ If the mains on led does not light up, check using the following procedure:
- ✓ Disconnect the mains cable;
- ✓ Check the externally accessible mains fuses;
- ✓ Disconnect the battery from the device as indicated in chapter 8.4;
- ✓ Connect a voltmeter to the free terminal caps;
- ✓ Connect a 1000 Ohm resistance in parallel with the voltmeter;
- ✓ Connect the mains cable: the reading should indicate a voltage of 13.65 Vdc± 5%;
- ✓ If the reading is outside the range of values indicated, replace the motherboard.

6.1.3 Internal circuit power supply

This consists of the following power supplies:

- ✓ +5 V generated by a switching type voltage regulator;
- ✓ 5 VI – VL to supply the patient input analogue circuits on the hybrid circuit (insulated part);
- ✓ + 3.3 V generated by a linear regulator to supply the control logic;
- ✓ + 3 V reference voltage for the A/D converter;
- ✓ VTPH voltage obtained from the battery to supply the thermal head. This voltage is limited to a current of 5A and stabilised in voltage at +26 Vdc enabled only when printing.

Testing internal circuit power supplies (ref sheet 3 el diag)

- ✓ Check fuse F1;
- ✓ If no power is supplied to the internal circuits, replace the motherboard.

6.1.4 ECG acquisition

This consists of the following parts:

- ✓ Patient input connector;
- ✓ Protection against defibrillator discharges;

- ✓ Signal polarisation circuit;
- ✓ Hybrid circuit for amplification, filter and clamp;
- ✓ 12 bit Ad converter, 5 microvolts per bit;
- ✓ Insulation photocoupler (double insulation).

6.1.5 Motor control

This consists of the following parts:

- ✓ Stroboscopic sensor control;
- ✓ Phase comparator between reference frequency and motor feedback;
- ✓ Current amplifier for motor power supply.

6.1.6 Input/output circuits

6.2 Battery

Lead battery

- ✓ The battery is protected against short circuits by a Pico SHF T5A fuse, voltage 12 Vdc, and capacity 2000 mAh, supplied by the manufacturer of the device.
- ✓ Complete recharging requires at least 24 hours or longer. The battery can be partially recharged, in this case to prolong the life of the battery it should be fully discharged and recharged every 2 months.
- ✓ Replace the battery with one of equivalent type, voltage and capacity.

Warning: *The battery must only be removed if the device is off and the mains supply cable disconnected. Do not dispose of a spent battery as ordinary refuse or litter.*

Note: *The operation of the device is not guaranteed if the battery is flat or missing.*

Note*: The configuration parameters and any stored ECGs are not lost when the battery is changed.*

Note: *Update the system date and time after replacing the battery.*

Battery check

Proceed as follows to check the efficiency of the battery:

- ✓ Leave the battery on charge for at least 24 hours;
- ✓ Disconnect the mains cable;
- ✓ Activate printing of an ECG in manual mode on 6 channels at 5 mm/s: if the device shows the battery is flat within the first 5 minutes the battery should be replaced.

6.3 Keyboard card

The keyboard consists of:

- ✓ 13 function keys;
- ✓ 32 alphanumeric keys;
- ✓ 1 mains on LED;
- ✓ 128 x 32 pixel graphic display LCD;
- ✓ CPU connection through bi-directional synchronous serial port.

Testing the keyboard card circuits

- ✓ Execution of keyboard self-test;
- ✓ Execution of display self-test;

6.4 Printer unit

This consists of the thermal printer head support and the mechanical elements required to position it correctly.

- ✓ 1728 dot high resolution printer head, 8 dots per mm;
- ✓ support;
- ✓ paper feed unit consisting of 2 direct current reduction gears connected in parallel, one of which equipped with stroboscopic speed control;
- ✓ mark detection sensor.

Testing the print unit

✓ Execution of printer self-test.

6.5 IR Module

✓ The function of the IR module is to transmit and receive data from an external PC. The IR module can be used to perform the following functions:

✓ Updating firmware (Loader)*;

✓ Batch ECG transmission (L.E.M.S.)*;

✓ Real time ECG transmission (R.T.E ir)*.

* Consult the specific manual for further information.

7 Trouble Shooting

Defect	Possible cause/symptom	Remedy
The device does not switch on in any mode.	• Mother board/keyboard card.	• Holding down the ON/OFF key, measure 12Vdc on J52 (keyboard connector) pin 3; if absent replace the keyboard card, if not, replace the motherboard.
The device does not switch on when in mains mode.	• Mains LED indicator off.	• Check mains fuses, if OK replace motherboard.
The device does not switch on when in battery mode.		• Check T5A fuse on motherboard. • Check efficiency of battery and replace if necessary.
The battery does not charge.	• The device has not been charged for long enough. • Mains LED indicator off. • Defective battery.	• Leave the device charging for at least 24 hours. • Check mains fuses, if OK replace motherboard. • Check efficiency of battery and replace if necessary. • Check T5A fuse on motherboard.
Keyboard keys not working..	• The key pressed not enabled for the specific function.	• Execute keyboard self test and if it fails replace keyboard card.
The paper feeds through without printing.	• Paper not suitable, without black page recognition mark.	• Check that original paper is being used. • Check the paper has been inserted correctly. • Check that the 26 Vdc VTPH power supply to the thermal print head is present when printing is active, if not, replace the mother board. • Check signals on test point table T8 are present. If good, replace thermal head unit, otherwise replace motherboard.
Anomalous printout.		• Clean thermal head. • Execute printer self-test, replace thermal head unit if some dots are missing.
Does not print automatically or does not paginate the trace correctly.	• Paper not suitable, without black page recognition mark.	• Clean mark sensor • Perform mark sensor calibration. • Replace print unit.
Paper feed defective, or paper finished message with paper present.		• Check paper guides are not damaged. • Clean rubber roller • Replace print unit.
EC signal disturbed or anomalous.	• Error message on display, on printout.	• See user manual.
The device stops during use.	• No functions operational, no commands accepted.	• Press reset button on right side of device.

8 How to dismantle and reassemble the device

8.1 General precautions

Disconnect the mains cable before opening the unit.
See chapter 15 (procedures for handling ESD components).
To reassemble the device, perform the operations described below in reverse order, ensuring that all subassemblies and connections are performed correctly.

8.2 Opening and closing the device (table T3)

- ✓ Remove the 9 fixing screws from the mobile base (T3 Ref. 1);
- ✓ Lift the mobile base of the device;
- ✓ Disconnect the two battery connections;
- ✓ Remove the lower mobile part.

Warning: *Respect the correct polarity of the battery connection: if the polarity should be inverted check the Pico SHF T5A fuse on the motherboard.*

8.3 Removing the mother board (table T5)

- ✓ Proceed following the instructions in chapter 8.2;
- ✓ Remove 2 screws (T5 Ref. 1);
- ✓ Lift the patient connector side of the board and disconnect the following:
  - the keyboard flat;
  - the thermal head flat;
  - the motor and mark sensor card flat;
  - the earth connector.

Warning: *Replacing the motherboard means that the paper feed speed and mark presence sensor must be recalibrated.*

8.4 Removing the battery (table T4)

- ✓ Proceed following the instructions in chapter 8.2;
- ✓ Remove the 2 screws attaching the battery to the housing (T4 Ref. 1);
- ✓ Remove the battery support (T4 Ref. 2);
- ✓ Remove the battery and replace.

8.5 Removing the keyboard card (table T5)

- ✓ Proceed as described in chapter 8.2.
- ✓ Remove 8 screws (T5 Ref. 3);
- ✓ Replace the keyboard card.

8.6 Removing the print unit (table T7A, T7B)

- ✓ Proceed as described in chapter 8.3.;
- ✓ Remove 2 screws (T1 Ref. 1);
- ✓ Remove 2 screws (T6 Ref. 1);
- ✓ Remove the print unit from door side.

Warning: *Replacing the print unit means that the paper feed speed and mark presence sensor must be recalibrated.*

8.7 Removing the print unit thermal head (table T7B)

- ✓ Proceed as described in chapter 8.6.
- ✓ Remove 2 screws (T7B Ref. 1);

Warning: *The thermal head is extremely sensitive to electrostatic potentials and the work procedures described in appendix A should be closely followed. The thermal head is aligned in the factory and requires no further calibration.*

8.8 Dismantling the paper guide door (table T1)

- ✓ Proceed as described in chapter 8.2.
- ✓ Loosen the 2 clamp screws (T5 Ref. 2);
- ✓ Position the paper guide door in a vertical position and remove the 2 locking nuts from the studs (T1 Ref. 2), remove the studs;
- ✓ Replace the paper guide door.

Warning: *tighten the 2 screws (table T5 Ref. 2)until fully tight, then unscrew one turn.*

Note: *If the roller is not clean and the paper door is on or incorrectly locked, the paper feed will not operate properly and the device will malfunction.*

8.9 Dismantling and replacing the keyboard membrane (table T1)

The keyboard membrane (T1 ref. 3) is an elastic membrane over the keyboard card that allows the keys to be pressed.
This self-adhesive plate is glued to the upper part of the device.
To replace it when worn, lift one corner with a sharp blade and tear off the case.
Remove any adhesive left on the case.
To fit a new membrane, centre it with the corners in its housing, and press lightly over the whole surface, ensuring the display protection window is correctly positioned.

Note*: A broken or cracked keyboard membrane compromises the safety of the device.*

9 Calibration and setting

9.1 General information

This device has a system to automatically set the paper feed speed and mark detection sensor.
The device does not require further setting.
The calibration system may be accessed from the service menu as described below.

9.1.1 Self-test

The device is pre-set to execute self-testing of the main functions: the access sequences for the various menus are guided on the display.
Two types of self-testing may be performed: USER (1) and SERVICE (2), according to the tests to be executed.

USER

To enter the self-testing menu, switch on the device, press the MENU key and select and confirm the TOOLS, SELF-TEST, USER(1) submenu using the arrow key (DOWN). The following tests are available in the operator section:

- Display: pixel scan. The presence of blank areas signifies faulty operation of the display.
- Keyboard: the position of the single keys is simulated in the display. Pressing a given key, the corresponding area of the display is highlighted in reverse. A lack of response in any one area indicates that the relative key is faulty.
- Printer: the system prints two triangular waves, the character set in the memory, and signals with different speeds and sensitivities. Irregularities in the printing system are indicated by the presence of non-continuous lines (burnt dots).
- Memory: a non-destructive test is performed on the memories (the data in the memory are not cancelled), and a report of the following type is then printed (all tests OK).

  <<< ar2100 adv MEMORY TEST >>>

  Boot : CRC OK

  Application : CRC OK

  Language : CRC OK

  Ram Memory : OK
- Info: The following items of information are printed: model identification, serial number of the device, details of software installed, version and language code, reference of any options installed.

SERVICE

To enter the self-testing menu, switch on the device, press the MENU key and select and confirm the TOOLS, SELF-TEST, SERVICE(2) submenu using the arrow key (DOWN). When the access code is requested, press the following keys: FILTER – AMPLITUDES – SPEED – START and confirm.
the following tests are available in the service section:

9.1.2 Mark calibration

Confirm the submenu MARK CALIBRATION (1), position the mark at a distance from the sensor (visible near the exit from the device), and confirm "enter"
The microprocessor automatically reads the sensor output voltages, voltage with white paper and black mark, and then sets the digital trimmer that regulates the photodiode current to the optimal settings and then stores them.
The mark calibration voltages are shown on the display, as is the numerical position of the digital potentiometer.

9.1.3 Speed calibration

Testing and setting

Select and firm the SPEED CAL. (2) submenus, and the speed to calibrate
The following messages then appear on the display: Output PWM0 Output – Freq = xxxx Hz with the possibility of selecting from: test – change – exit.
Confirming the "test" command enables the paper feed and the print unit emits a 1 impulse per second signal. If the speed has to be calibrated, select "change" and increase or decrease the frequency to set the paper feed speed entered. When the speed has been set correctly, select and confirm with "exit".
The permitted tolerance values for the various paper feed speeds are as follows:

50 mm/s ± -5%

25 mm/s ± -5%

5 mm/s ± -10%

9.1.4 Metres of paper printed

Displays the number of metres of paper printed.

9.1.5 Firmware upgrades

Enables upgrading of the instrument's internal firmware.

The firmware upgrade menu can be accessed from the main menu, pressing the Shift + S keys together.

***Note**: Refer to the "Loader" programme manual for further information.*

10 Periodic maintenance

The **ar2100 adv** electrocardiograph has been designed to assure a high degree of reliability during the life cycle of the product.
Any incorrect conditions of use or anomalous operation will be signalled by messages on paper and on the display.

10.1 Inspection frequency

To guarantee a long and safe duration, the instrument and its accessories must be periodically inspected and checked.
Table 9 indicates the type and frequency of controls required, based on normal use of the electrocardiograph (about 4000 ECG recordings per year).

***Warning**: Check immediately if events occur that are not attributable to normal use.*

General and safety tests

Type of operation	**Frequency - months**
- full discharging and charging of battery	2
- check and clean printer head	3
- visual inspection of the device, patient cable and accessories	6
- execution of self-test	6
- check and clean paper roller	12
- check paper speed	12
- check keys and keyboard	12
- check keyboard membrane	12
- clean paper compartment and mark presence sensor	12
- check patient cables and electrodes	12
- check whole amplification chain (sensitivity test)	12
- check battery	12
- calibrations	12
- check leakage currents	24

Table 9

11 Cleaning and disinfection

11.1 Cleaning the device, electrodes and patient cable

- *Device:* use a cloth dampened with water or denatured ethyl alcohol. Do not use other chemical products or household detergents.
- *Electrodes:* remove the electrodes from the patient cable and wash under running water. Do not scratch the electrodes and do not wash the leads box and the patient socket.
- *Patient cable:* do not immerse in water, use a cloth dampened with alcohol or an equivalent solvent.

Note: *the device cannot be sterilized! The electrodes can be sterilized with ethylene oxide.*

11.2 Clean thermal head

To clean the printer thermal head correctly use a cloth slightly dampened with alcohol or an equivalent solution with the device off.

Proceed as follows:

- ✓ open the paper guide door;
- ✓ pass the cloth over the dots of the thermal head without pressing too hard.

Warning: *the printer thermal head is extremely sensitive to electrostatic potentials. Do not touch it for any reason. If necessary, handle it after connecting to a mass via a suitable protective bracelet or belt.*

11.3 Cleaning the paper guide roller

To clean the paper guide roller correctly, open the door and use a soft cloth lightly dampened with alcohol or an equivalent solvent, turning the roller to clean the whole surface.

11.4 Cleaning the mark recognition sensor

To clean the mark recognition sensor correctly use a cloth slightly dampened with alcohol or an equivalent solution with the device off.

Proceed as follows:

- ✓ open the paper guide door;
- ✓ pass the cloth over mark recognition sensor without pressing too hard.

12 Spare parts list

The code numbers of the spare parts are listed in table 12.1.
The spare part code is also indicated on the label identifying the main subassemblies inside the device.
To order a spare part, use the corresponding code number.

List of spare parts for the ar2100 adv device code 80600061

Spare part code	Description	Ref	Note
69701022	12V 2Ah battery		
69700788	0.5 AT 5x20 mm fuse (10 pieces)		Installed on mains plug
69701148	5 A SMF SLO-BLO SMD fuse (10 pieces)		Installed on mother board
69701404	Case Complete		Excluding keyboard membrane
69701405	Printer sensor and motor unit		
69701406	Print head with frame		
69701034	Paper guide		
69701064	Paper spindle		
69701407	Mother board		*
69701408	Keyboard with display		
69701018	Mains plug		
69701409	Keyboard membrane		

Table 12.1

* The replacement motherboard is supplied complete with basic software in English and S/N 00000000.
To reinstall the configuration before the replacement of the motherboard, the following data must be supplied:

- ✓ device code number (REF)
- ✓ serial number (SN)
- ✓ language
- ✓ options purchased

et medical devices will send the corresponding firmware (binary file to load through the Loader application), which will install the correct S/N and enable the options previously purchased.

Warning: Once the firmware has been reloaded with a specific S/N it cannot be further modified.

Note: *The data requested can be printed out directly by the instrument, using the info function on the self-test menu.*

13 Interconnections with medical systems

The device has an RS232 infrared interface to communicate with a PC equipped with specific programmes.

This type of connection guarantees the insulation required for connection with medical systems.

The communication with a PC occurs through a proprietary protocol – a standard IRDA protocol cannot be used.

et medical devices has validated the following IR interface devices for installation on the COM port of a PC.

- Extended System mod. ESI 9680B JETEYE
- ACTiSYS ACT-IR220L

Note: Do not install the drivers *on the cd rom supplied on the PC. If the drivers should have been inadvertently installed, uninstall them.*

14 ECG ar 2100 adv technical characteristics

A.c. mains power supply	Device with Class I power supply 230 V ± 10% 50/60 Hz 115 V ± 10% 50/60 Hz
Maximum current absorbed	0.5 mA at 115 V ~ ±10% 0.25 mA at 230 V ~ ±10%
Mains protection	Fuse: T 0.5 A
Internal power source	12 V - 2Ah rechargeable lead battery
Internal power supply protection	Pico fuse SHF SLO-BLO T 5 A Littelfuse
Applied part	CF type
Defibrillation protection	Internal
Input dynamic	± 300 mV @ 0 Hz. ± 10 mV in the passband
Input impedance	> 100 MΩ on each electrode
Common mode rejection	> 100 dB with electrode impedance balanced
Frequency response	0,5 ÷ 150 Hz (-3dB) with anti-drift filter
Time constant	3.3 s
Acquisition	12 bit 1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters Resolution 5 μV/bit
Leads	12 STANDARD leads 12 CABRERA leads 8 acquired, 4 derived (III, aVR, aVL, aVF)
Signal memory	10 seconds for each lead in auto isochronous
Recording sensitivity	5 – 10 – 20 mm/mV ± 5%, auto* *2,5 - 5 – 10 – 20 mm/mV ± 5%, *dependent on number of channels printed*
Writing system	Thermal printer, 8 dot/mm Usable print height 210 mm
Print channels	3 – 6 – 12
Paper feed rate	5 mm/s ± 10% 25 – 50 mm/s ± 5%
Heat sensitive paper	roll: in 210x280 mm (width x length) sheets, gridded, length 17 mm *Z-fold pack*: in 210x150 mm (width x length) sheets, gridded, length 30 mm *Z-fold pack*: in 210x300 mm (width x length) sheets, gridded, length 60 mm
Pacemaker recognition	Records impulse in compliance with IEC 60601-2-51/Ed. standards 1
Filters	*Mains interference:* Modified notch digital filter 50 – 60 Hz with response @ 32 Hz (-3dB) linear phase – on/off filter. *Anti-drift:* 0.5Hz high pitch linear phase filter always on cannot be switched off.
Serial interface	Infrared
Keyboard	Membrane keyboard with 13 function keys , 32 alphanumeric keys and 1 power-on indicator Led
Display	120x32 dot backlit graphic LED
Optional programmes	ECG HES interpretation and parameter calculation: Developed at the Medizinische Hochschule, Hanover, Germany
Type of use	continuous
Operating modes	*manual:* acquisition and printing in real time *Automatic* : simultaneous acquisition *ECG Autotimer* acquisition at user-defined intervals
Optional	*Paper Saving* signal acquisition in simultaneous mode with possibility of copying or storing on PC. *PC-ECG:* signal transmission in real time to Personal Computer with R.T.E. programme *Arrhythmia Monitor* signal monitoring with recognition of arrhythmic events *HRV analysis* analysis RR interval variability in a specific period.
Battery capacity	*Internal battery:* 1hour with printing in 6 channels mode
Recharging time	*Internal battery:* 24 hours or more 100%
Housing protection category	IP 20
Environnemental conditions: - operation - transport and storage	 *Environment temperature:* from +10°C to +40°C *Relative humidity:* from 25% to 95% (without condensation) *Atmospheric pressure:* from 700hPa to 1060 hPa *Environment temperature:* from –10°C to +40°C *Relative humidity:* from 10% to 95% (without condensation) *Atmospheric pressure:* from 500 to 1060 hPa
Dimensions	325 x 80 x 345 mm (length x height x depth)
Weight	4800 grams with battery, without paper

Conformity to standards	EN 60601-1: 1990 EN 60601-1/A1: 1992 EN 60601-1/A2: 1995 EN 60601-1/A13: 1995 General standards for safety of electromedical equipment EN 60601-1-2: 1993 *Standards on electromagnetic compatibility of electromedical equipment* EN 60601-2-25: 1995 EN 60601-2-25/A1: 2000 Particular safety standards for electrocardiographs EN 60601-2-51/Ed.1: 2001 Particular standards on essential recording and analysis performance safety of single and multichannel electrocardiographs

15 APPENDIX A

15.1 Procedures for manipulating and storing components (ESD)

All modern electronic components, particularly those based on CMOS technology, may be irreparably damaged by even modest electrostatic discharges.

Precautions must be taken against electrostatic discharges when handling and working on electronic components sensitive to electrostatic discharges. ELECTROSTATIC SENSITIVE DEVICE (ESD).

Staff involved in checking, warehousing, shipping and assembly operations must be earthed through a suitable conductive bracelet compliant with safety standards. If this precaution cannot be taken, the operator must wear suitable antistatic shoes or boots.

Work equipment must be earthed.

Tables, work surfaces and other surfaces on which components are handled must be covered in conductive material and earthed.

All tables and work surfaces must be covered with a layer of conductive material and earthed.

The person performing the repair must be earthed with a suitable protective bracelet compliant with safety regulations.The material must be contained in suitable antistatic bags or containers, and labelled according to MIL STD 129J. The containers must guarantee adequate protection against impact and handling during transport.

All E.S.D. components must be stored in their original boxes and kept in special metal containers. While stored in the warehouse, electronic components must be kept in their original packaging.

Any containers used must be exclusively in metal and/or conductive material. If handled directly, the personnel must adopt the precautions specified above.

During handling cards must be stored in suitable antistatic containers.

Each component sensitive to electrostatic discharges will be identified by the abbreviation ESD.

In the Warehouse area containers are labelled with a suitable symbol.

Follow all the instructions in this procedure when dealing with E.S.D. components.

Warning: *The manufacturer is not responsible for any damage to the device caused by insufficient or inadequate treatment, handling or work methods.*

16 APPENDIX B

16.1 Figures and illustrated tables

T1 Top view
T2 Side view
T3 Bottom view
T4 Lower housing
T5 Upper housing
T6 Upper housing
T7A Writing system
T7B Print head assembly
T8 Thermal head test point

17 Revision Sheet

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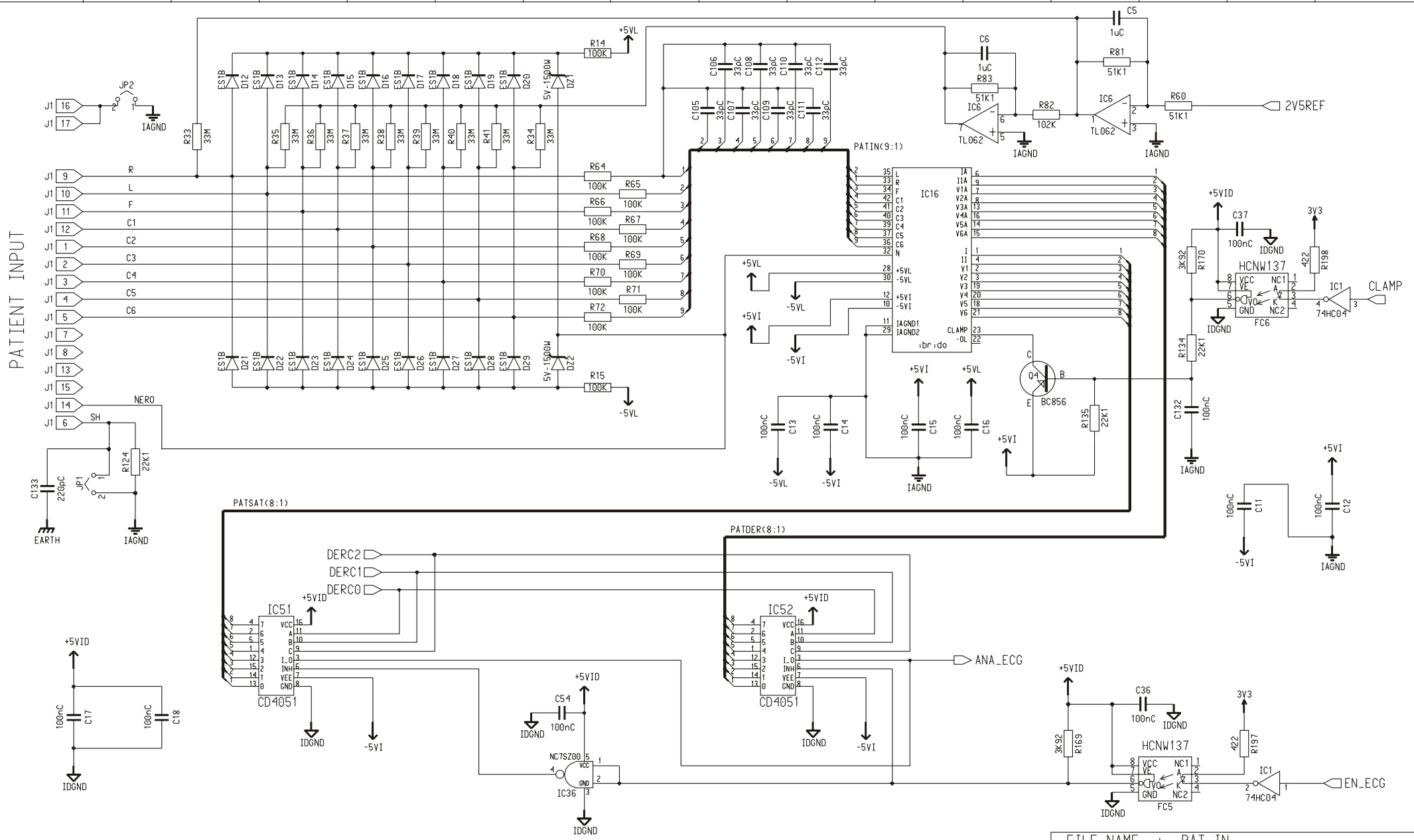
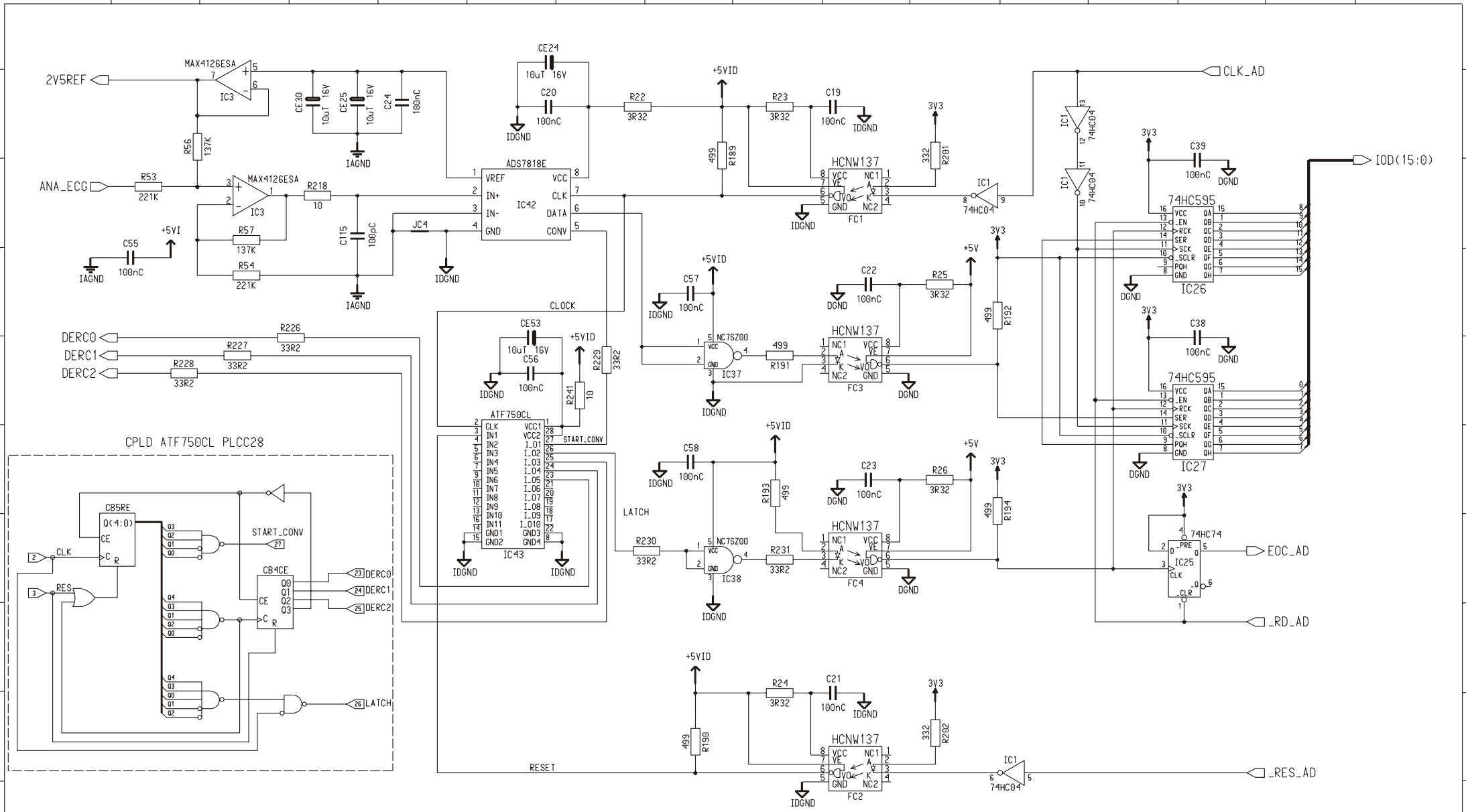


UNUSED GATE/S
NOTE : INPUT DYNAMICS = + / -10 mV
INPUT CUTOFF FREQUENCY = 190Hz
GAIN = 390

REF. DES	DEVICE	POWER PINS +5VL	-5VL	3V3	DGND	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE
IC6	TL062	8	4								
IC1	74HC04			14	7						

FILE NAME : PAT_IN		
PCB CODE : 3PCB16001808/A		
DES. : MOTHER BOARD FOR AR 2100 VIEW		
DRAWER C F	COD. : 20002764/A	
CHECK		
DATE 04.02.2003	DATE REV. 10.04.2003	SHEET 1 OF 12

et medical devices



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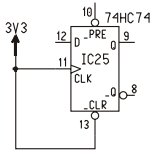
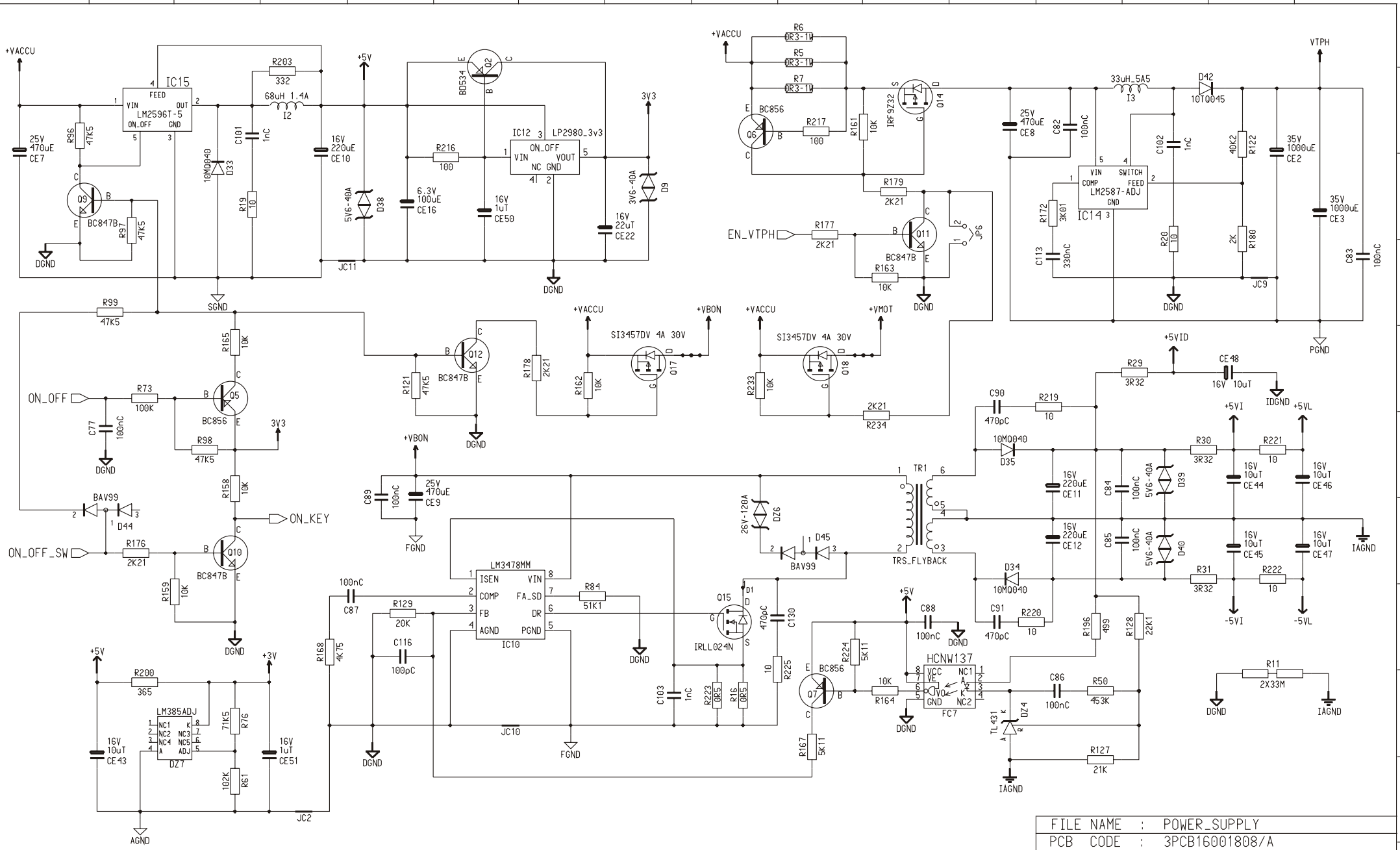


REF. DES	DEVICE	POWER PINS +5VI	IAGND	3V3	DGND	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE
IC3	MAX4126	8	4								
IC1	74HC04			14	7						
IC25	74HC74			14	7						

FILE NAME : AD_CONV
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
COD. : 20002764/A
CHECK
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 2 OF 12

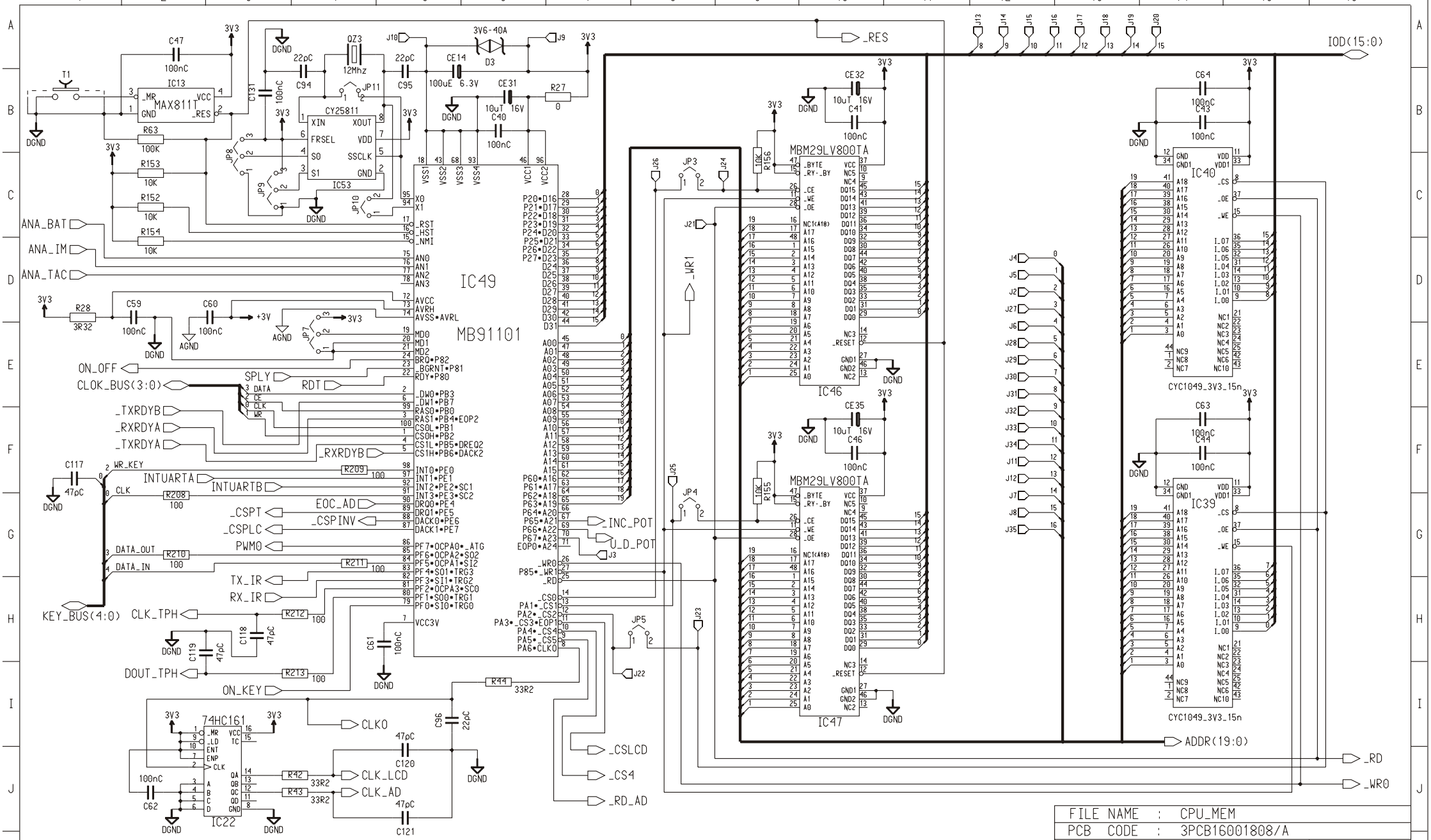


UNUSED GATE/S

REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE

FILE NAME : POWER_SUPPLY
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
COD. : 20002764/A
CHECK
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 3 OF 12

et medical devices



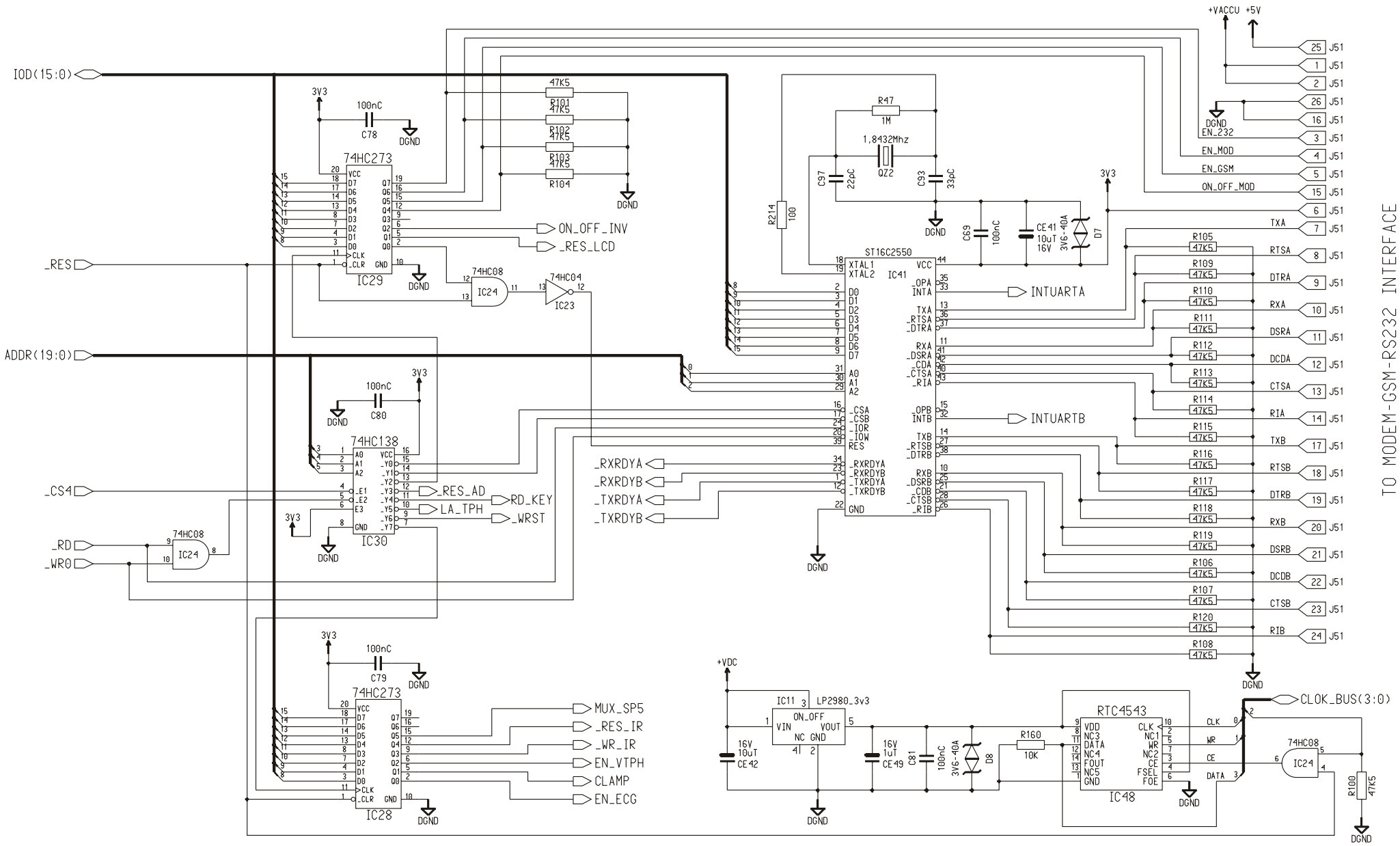
UNUSED GATE/S
74HC04 IC23

REF. DES	DEVICE	POWER PINS 3V3	DGND	VDD	VEE
IC23	74HC04	14	7		

REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE

FILE NAME : CPU_MEM		
PCB CODE : 3PCB16001808/A		
DES. : MOTHER BOARD FOR AR 2100 VIEW		
DRAWER C F	COD. : 20002764/A	
CHECK		
DATE 04.02.2003	DATE REV. 10.04.2003	SHEET 4 OF 12

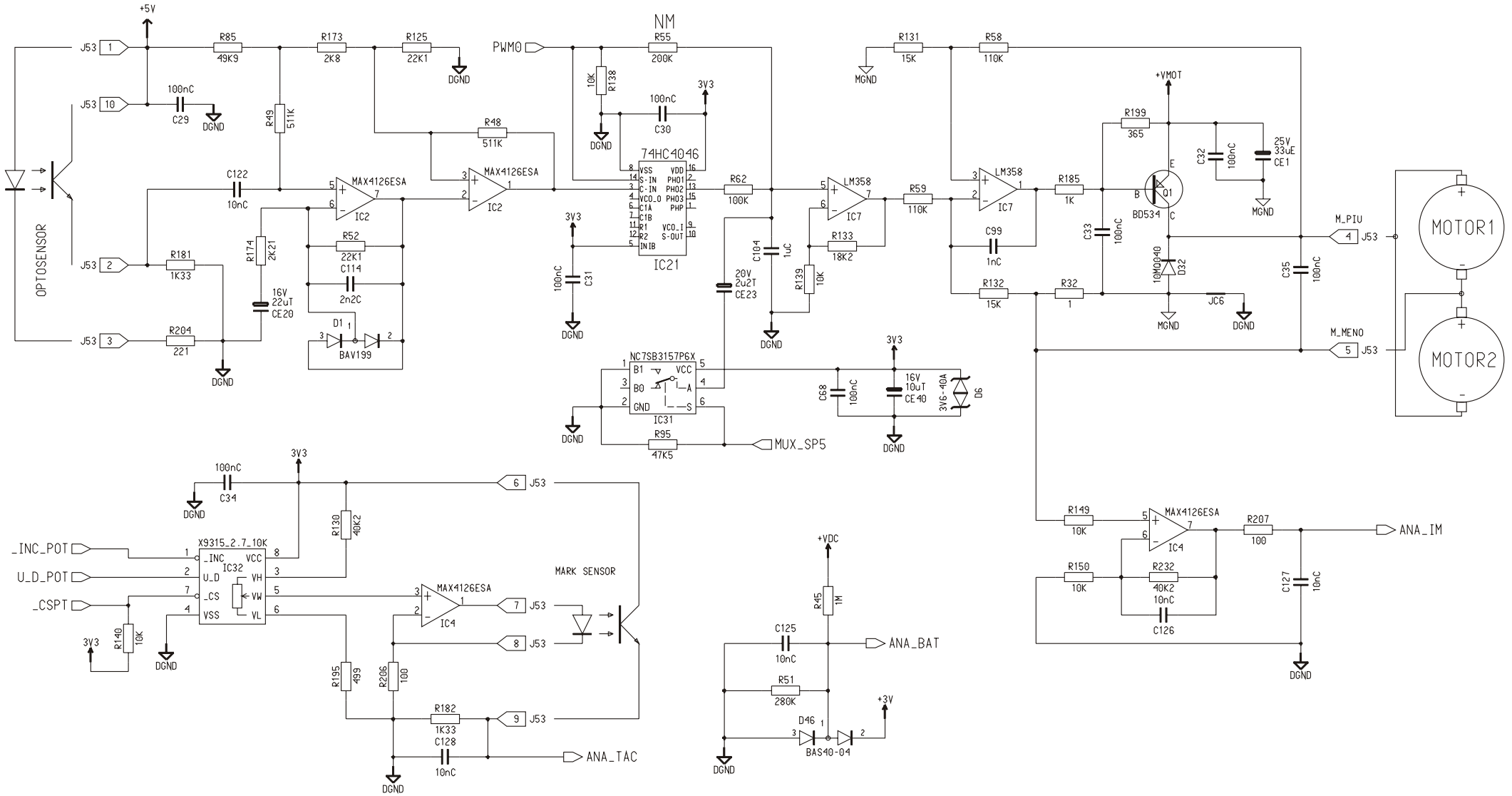
et medical devices



UNUSED GATE/S

REF. DES	DEVICE	POWER PINS 3V3	DGND	VDD	VEE	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE
IC24	74HC08	14	7								
IC23	74HC04	14	7								

FILE NAME : SERIAL_INT
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
CHECK
COD. : 20002764/A
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 5 OF 12

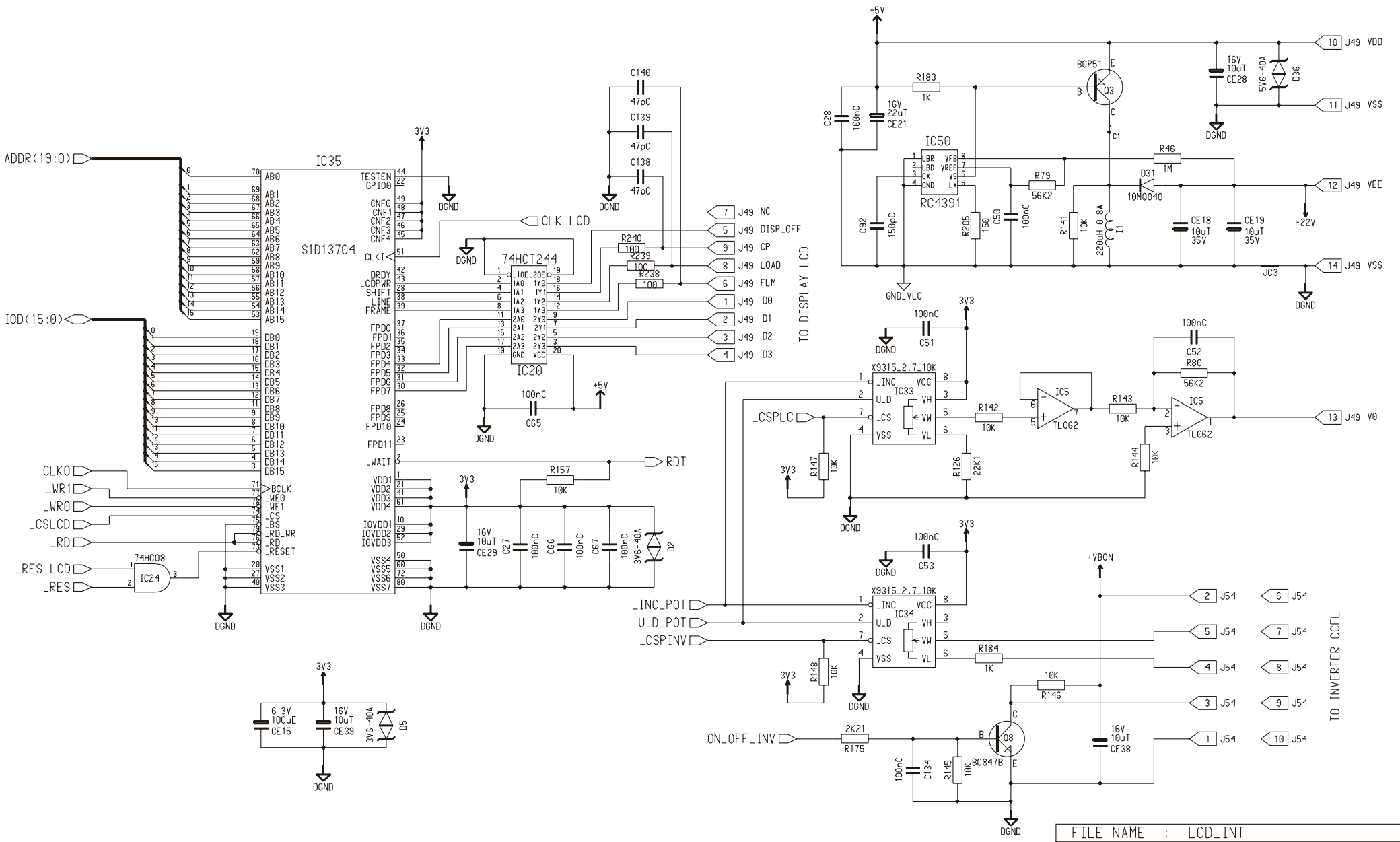


UNUSED GATE/S

REF. DES	DEVICE	POWER PINS 3V3	DGND	+VBON	MGND	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE
IC2 - IC4	MAX4126	8	4								
IC7	LM358			8	4						

FILE NAME : M_SPEED
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
COD. : 20002764/A
CHECK
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 6 OF 12

et medical devices

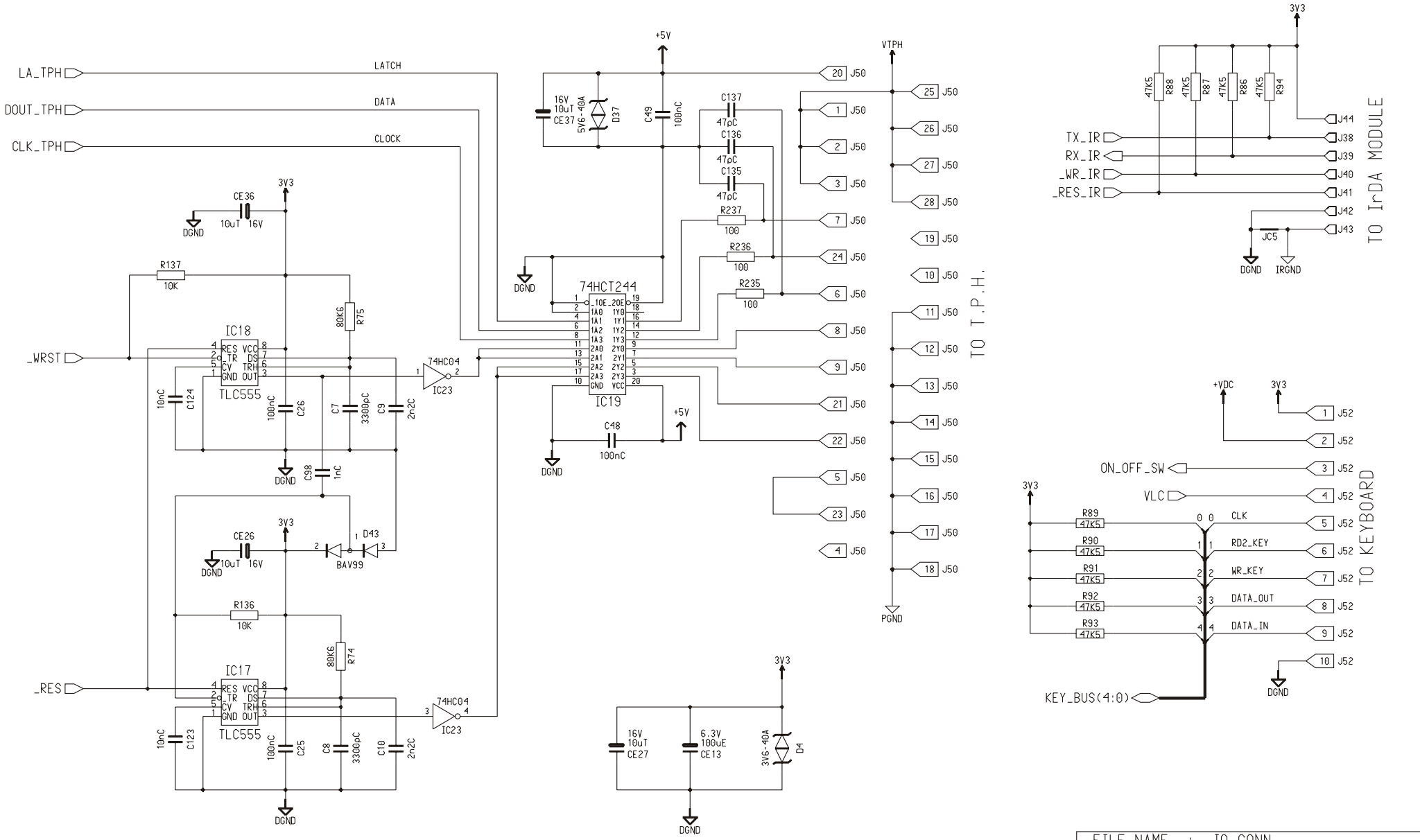


UNUSED GATE/S

REF. DES	DEVICE	POWER PINS +5V	-22V	3V3	DGND	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE
IC5	TL062	8	4								
IC24	74HC08			14	7						

FILE NAME : LCD_INT
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
CHECK
COD. : 20002764/A
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 7 OF 12

et medical devices



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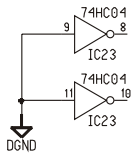

REF. DES	DEVICE	POWER PINS 3V3	DGND	VDD	VEE	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE
IC23	74HC04	14	7								

FILE NAME :	IO_CONN
PCB CODE :	3PCB16001808/A
DES. :	MOTHER BOARD FOR AR 2100 VIEW
DRAWER	C F
COD. :	20002764/A
CHECK	
DATE	04.02.2003
DATE REV.	10.04.2003
SHEET	8 OF 12

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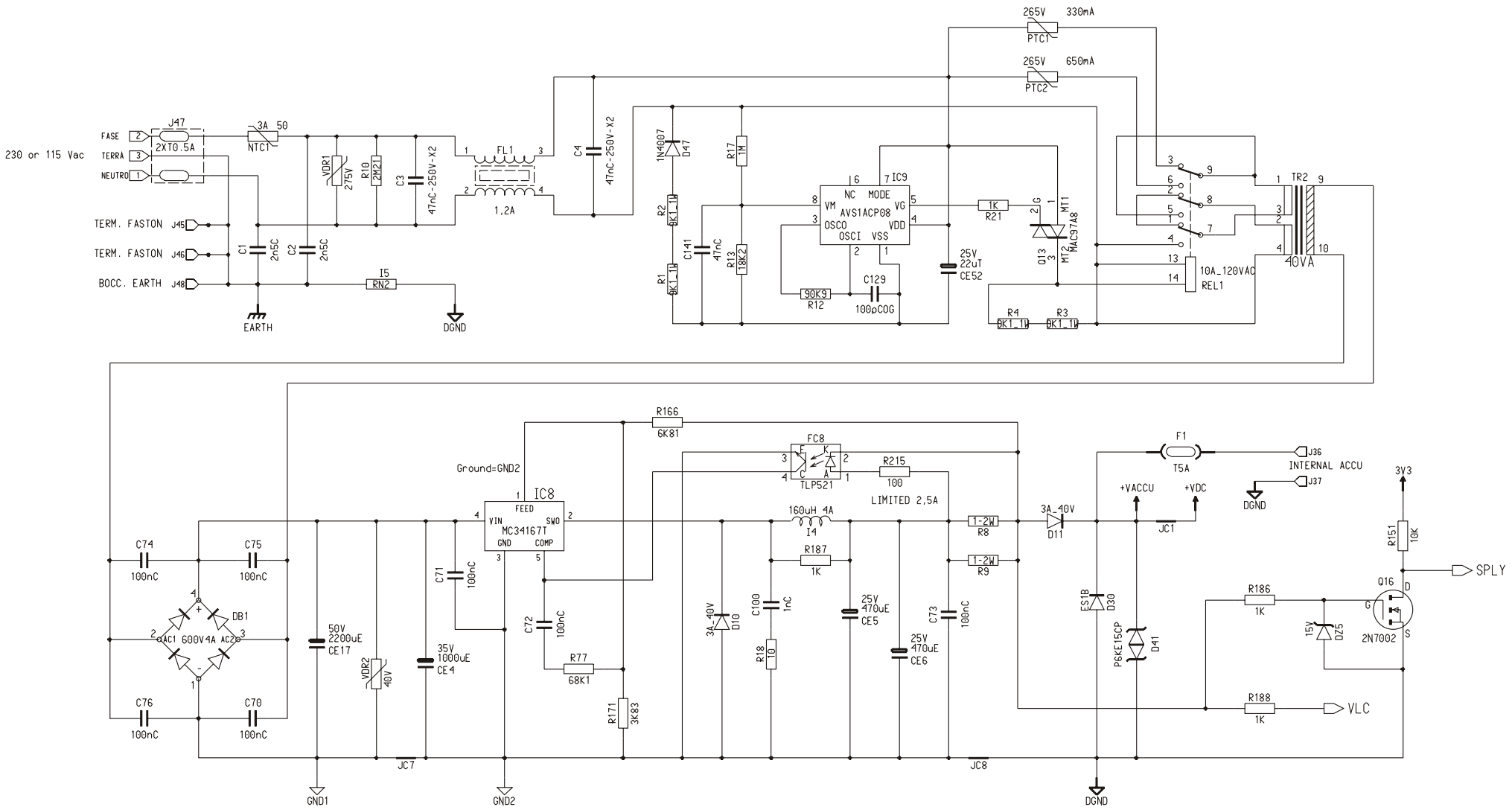
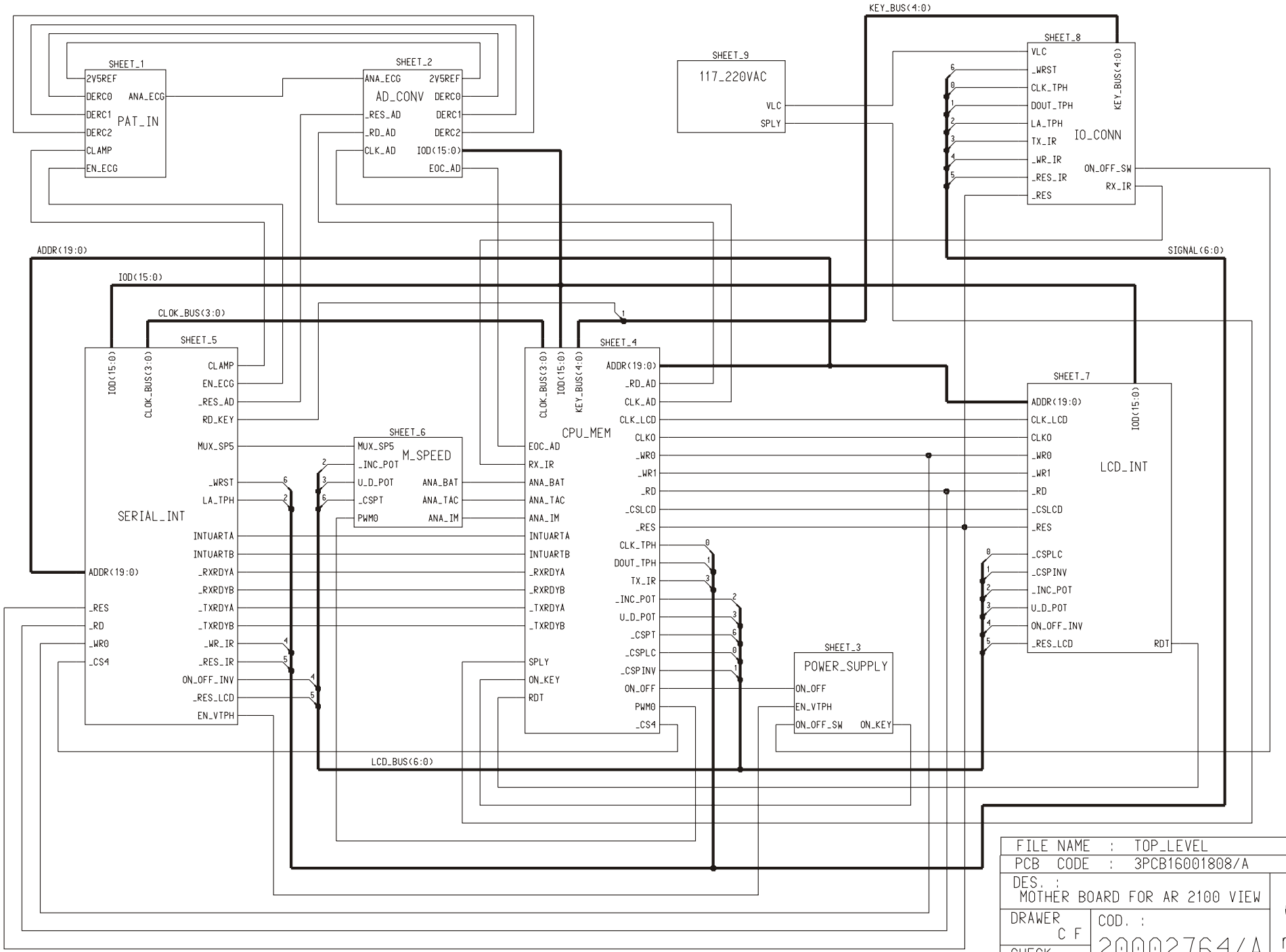


UNUSED GATE/S

REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE	REF. DES	DEVICE	POWER PINS VCC	GND	VDD	VEE

FILE NAME : 117_220vac
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
COD. : 20002764/A
CHECK
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 9 OF 12

et medical devices


SHEET_1
2V5REF
DERC0
DERC1
DERC2
CLAMP
EN_ECG
ANA_ECG
PAT_IN
SHEET_2
ANA_ECG
2V5REF
AD_CONV
_RES_AD
_RD_AD
CLK_AD
DERC0
DERC1
DERC2
IOD(15:0)
EOC_AD
SHEET_9
117_220VAC
VLC
SPLY
KEY_BUS(4:0)
SHEET_8
VLC
_WRST
CLK_TPH
DOUT_TPH
LA_TPH
TX_IR
_WR_IR
_RES_IR
_RES
IO_CONN
KEY_BUS(4:0)
ON_OFF_SW
RX_IR
ADDR(19:0)
IOD(15:0)
CLOK_BUS(3:0)
SIGNAL(6:0)
SHEET_5
IOD(15:0)
CLOK_BUS(3:0)
CLAMP
EN_ECG
_RES_AD
RD_KEY
MUX_SP5
_WRST
LA_TPH
SERIAL_INT
INTUARTA
INTUARTB
_RXRDYA
_RXRDYB
_TXRDYA
_TXRDYB
ADDR(19:0)
_RES
_RD
_WR0
_CS4
_WR_IR
_RES_IR
ON_OFF_INV
_RES_LCD
EN_VTPH
SHEET_6
MUX_SP5
_INC_POT
U_D_POT
_CSPT
PWM0
M_SPEED
ANA_BAT
ANA_TAC
ANA_IM
SHEET_4
CLOK_BUS(3:0)
IOD(15:0)
KEY_BUS(4:0)
CPU_MEM
EOC_AD
RX_IR
ANA_BAT
ANA_TAC
ANA_IM
INTUARTA
INTUARTB
_RXRDYA
_RXRDYB
_TXRDYA
_TXRDYB
SPLY
ON_KEY
RDT
ADDR(19:0)
_RD_AD
CLK_AD
CLK_LCD
CLKO
_WR0
_WR1
_RD
_CSLCD
_RES
CLK_TPH
DOUT_TPH
TX_IR
_INC_POT
U_D_POT
_CSPT
_CSPLC
_CSPINV
ON_OFF
PWM0
_CS4
SHEET_3
POWER_SUPPLY
ON_OFF
EN_VTPH
ON_OFF_SW
ON_KEY
SHEET_7
ADDR(19:0)
CLK_LCD
CLKO
_WR0
_WR1
_RD
_CSLCD
_RES
IOD(15:0)
LCD_INT
_CSPLC
_CSPINV
_INC_POT
U_D_POT
ON_OFF_INV
_RES_LCD
RDT
LCD_BUS(6:0)
FILE NAME : TOP_LEVEL
PCB CODE : 3PCB16001808/A
DES. : MOTHER BOARD FOR AR 2100 VIEW
DRAWER C F
CHECK
COD. : 20002764/A
DATE 04.02.2003
DATE REV. 10.04.2003
SHEET 10 OF 12
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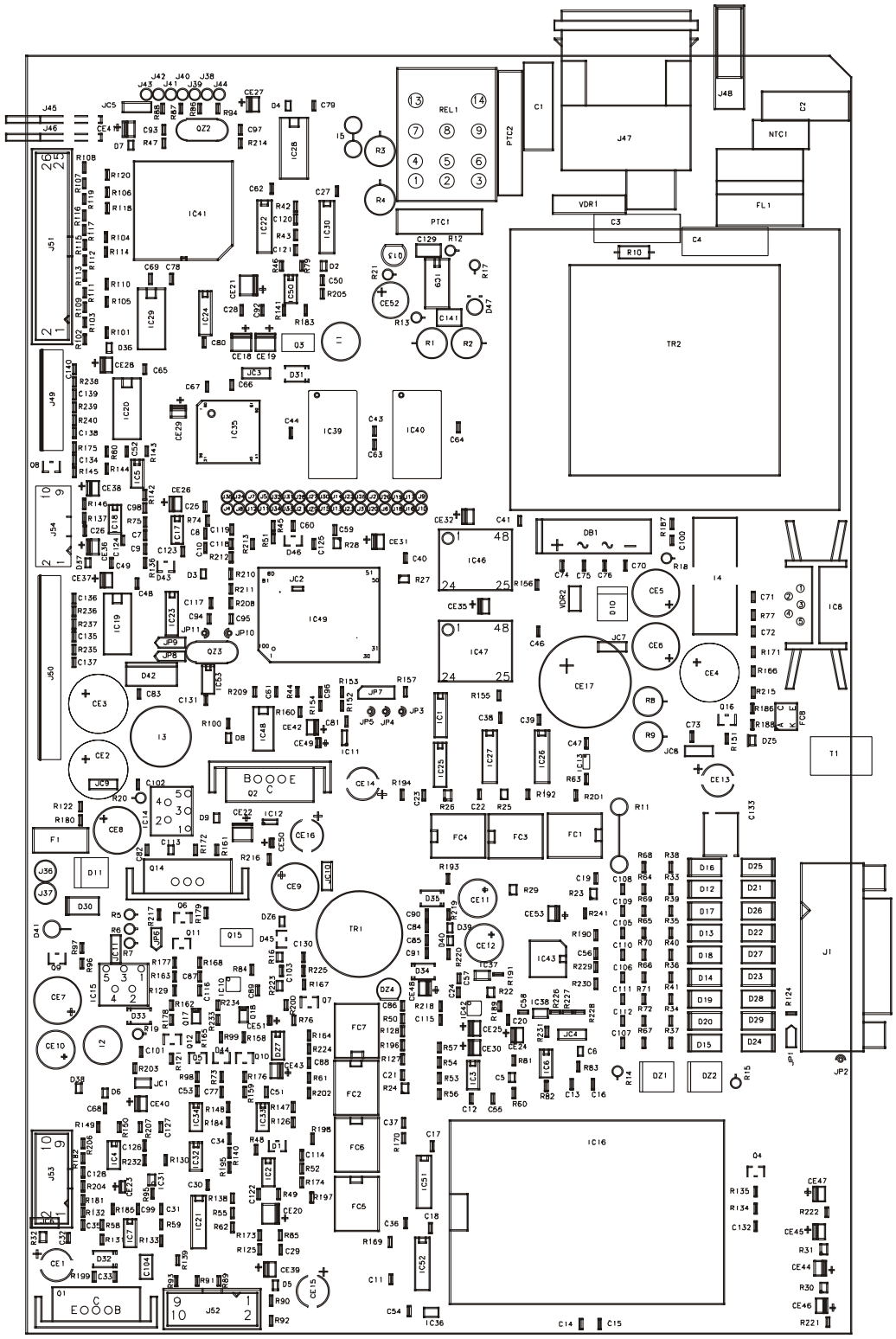
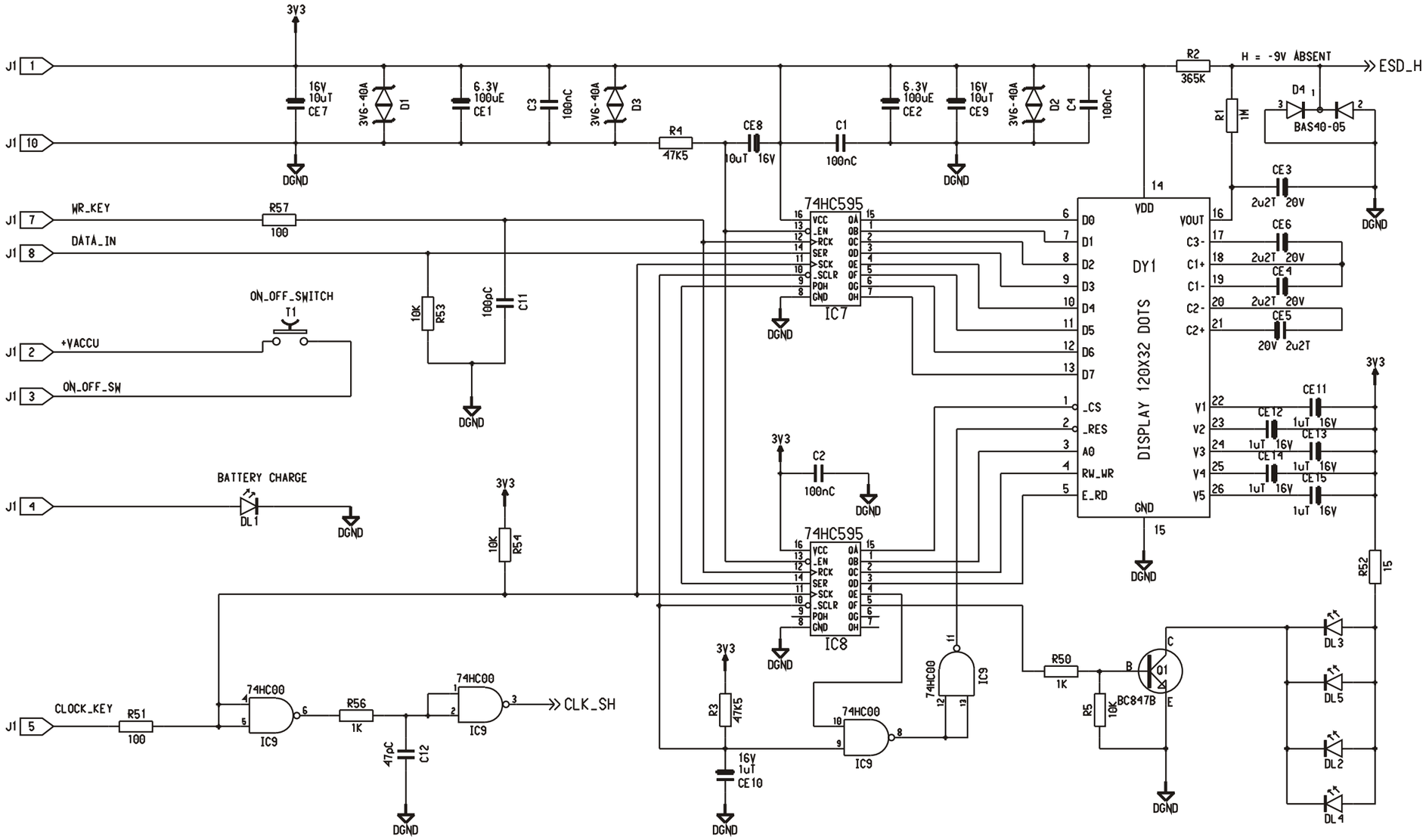
ALL RIGHTS RESERVED



DES.: MOTHER BOARD FOR AR 2100 VIEW				et Medical Devices spa	
LAYER N° 4					
FILE NAME AR_2100_3PCB_A					
PCB REFERENCE 3PCB16001808/A				CAVARENO (TN)-ITALY	all rights reserved
DRAWER	CHECK	DATA 04.02.2003		SHEET 11 OF 12	SCALA 1 : 1
G.S		DATA REV 10.04.2003		COD. 20002764/A	



UNUSED GATE/S	REF. DES	DEVICE	POWER PINS				REF. DES	DEVICE	POWER PINS			
			3V3	DGND	VDD	VEE			VCC	GND	VDD	VEE
	IC9	74HC00	14	7								

FILE NAME	: TAST_2100_ADV_2PCB
PCB CODE	: 2PCB16001812
DES.	keyboard
	AR2100 ADV
DRAWER	C F
COD.	: 20002773
CHECK	
DATE	15.10.2002
DATE REV.	
SHEET	1 OF 5

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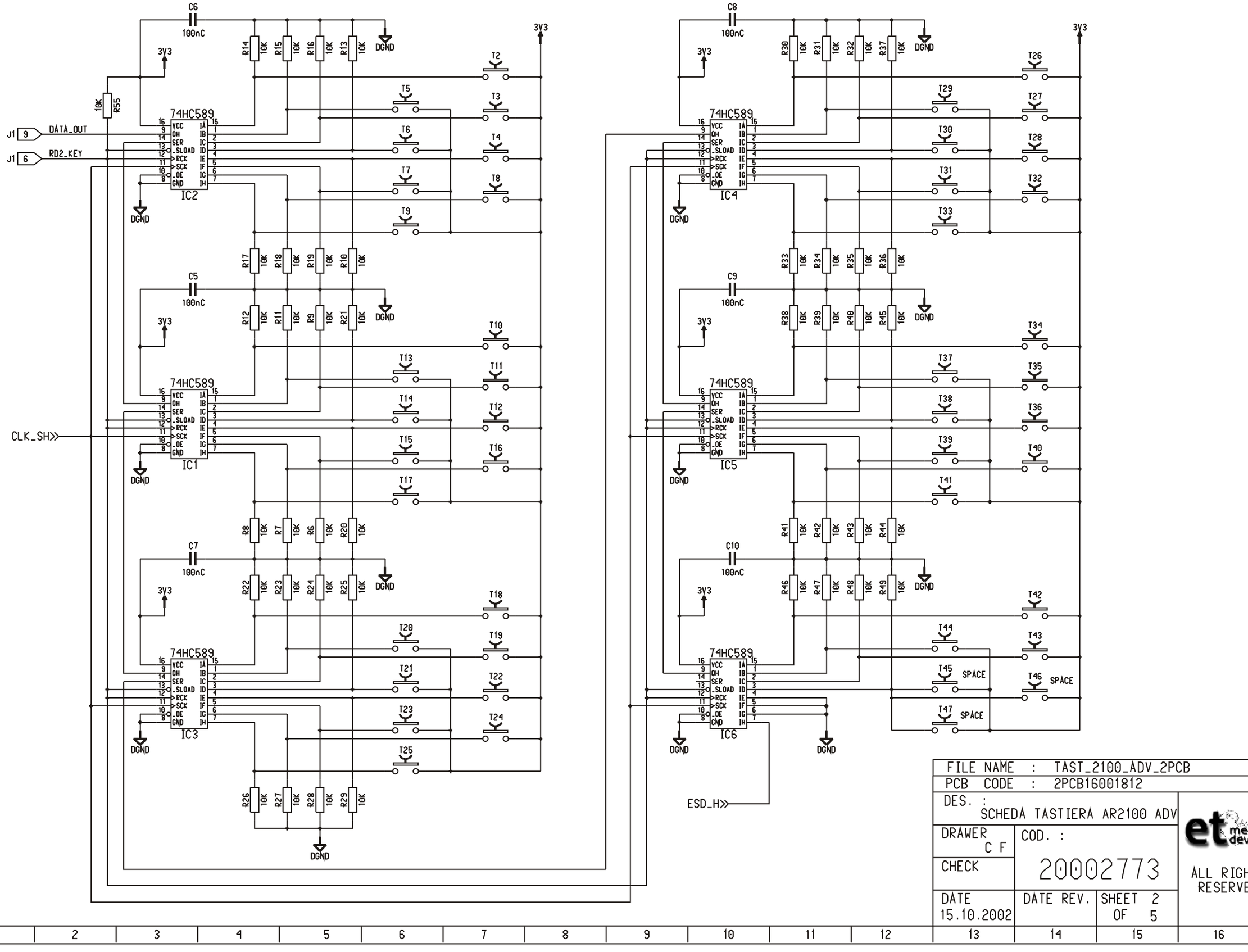
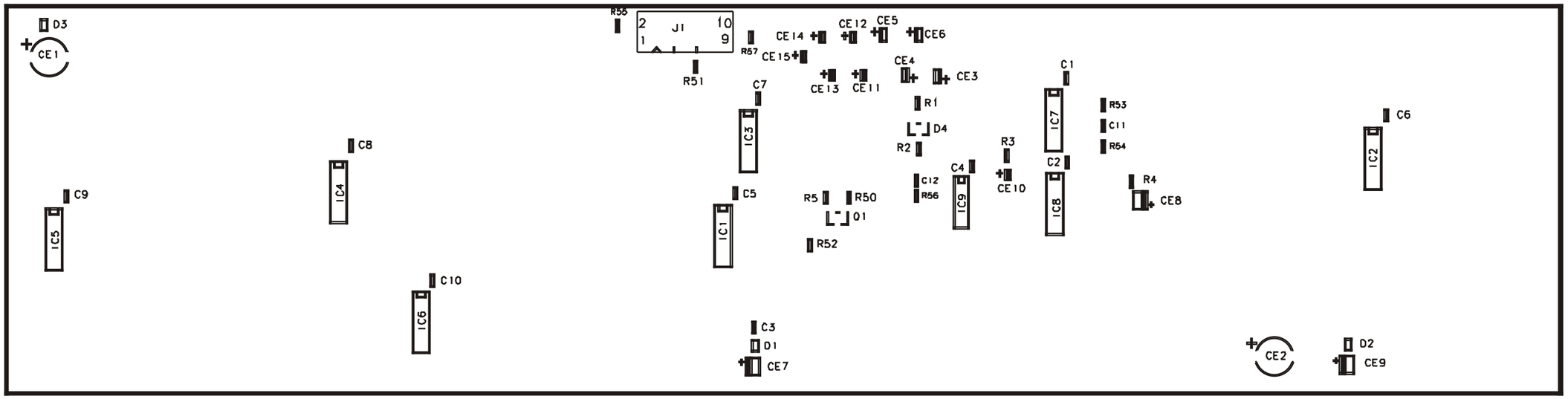
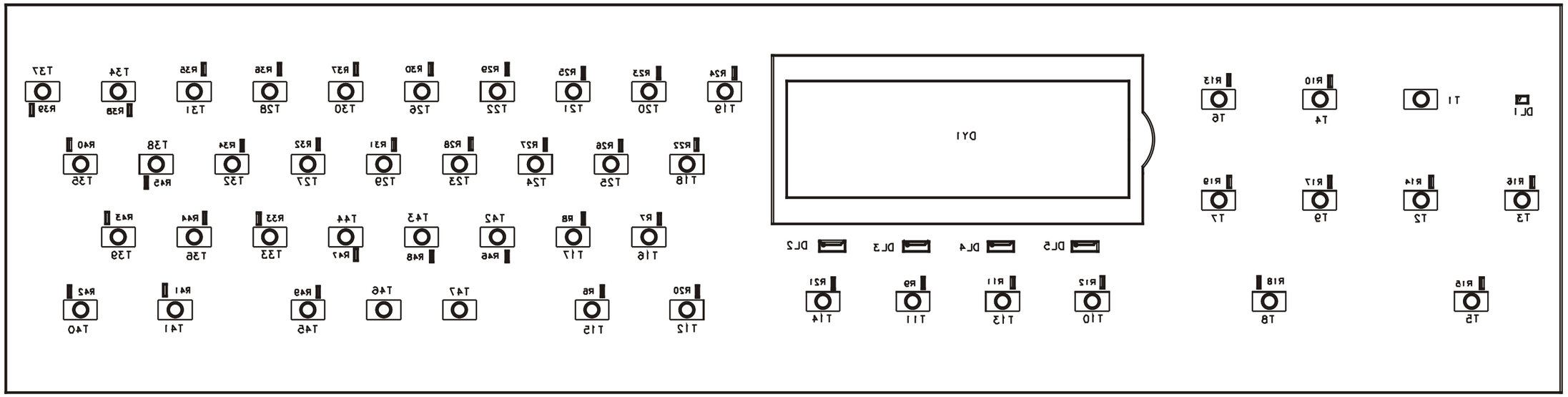


FILE NAME : TAST_2100_ADV_2PCB			
PCB CODE : 2PCB16001812			
DES. : SCHEDA TASTIERA AR2100 ADV			
DRAWER C F	COD. : 20002773		
CHECK			
DATE 15.10.2002	DATE REV.	SHEET 2 OF 5	



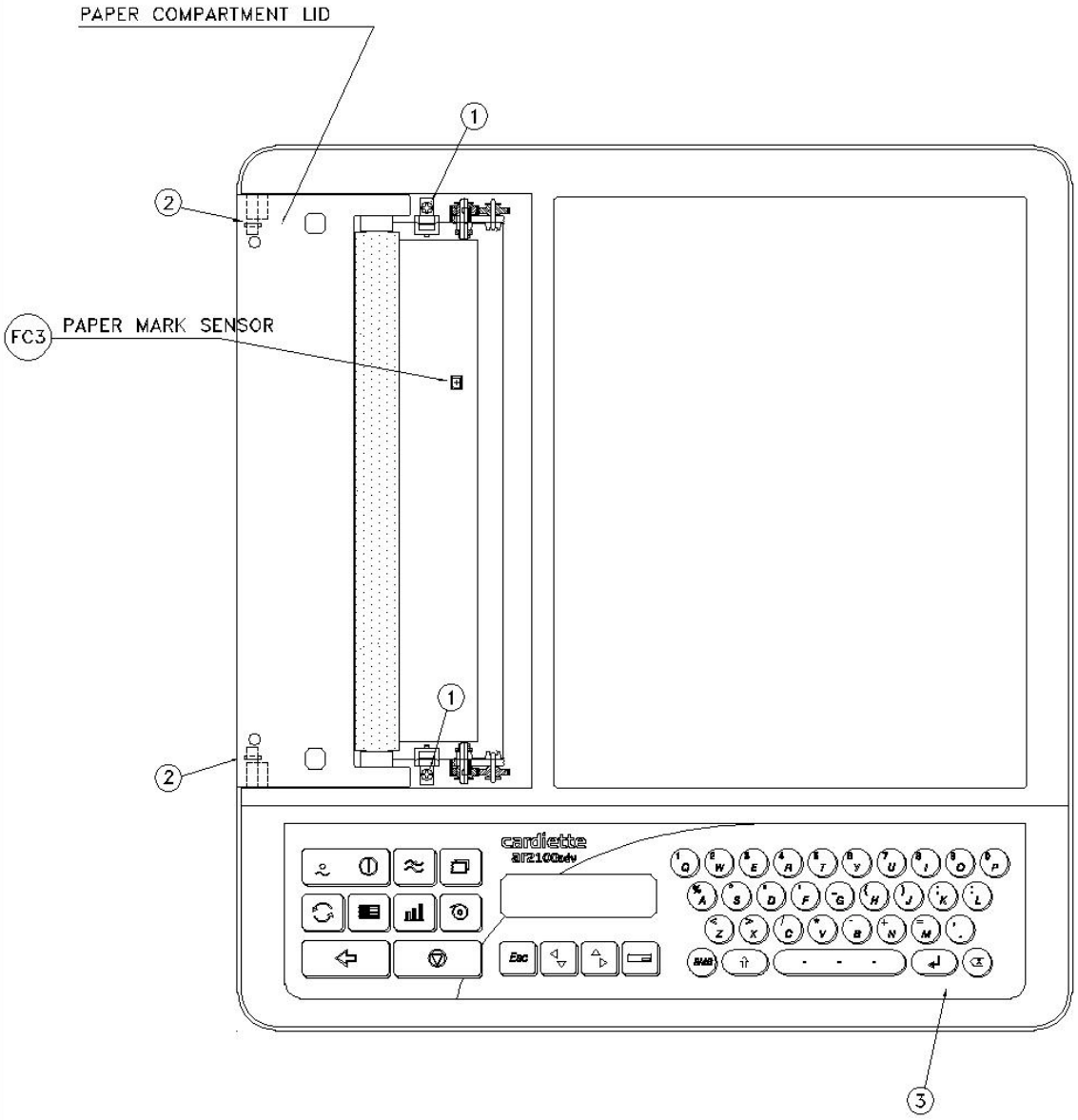
DISEGNO CIRCUITO VISTA LATO COMPONENTI						
DES.: SCHEDA TASTIERA AR 2100 ADV					et medical devices	
LAYER N° 2						
FILE NAME TAS_2100_ADV_2PCB						
PCB REFERENCE 2PCB16001812					CAVARENO (TN)-ITALY	all rights reserved
DRAWER	CHECK	DATA 15.11.2002			SHEET 3 OF 5	SCALA 1 : 1
GS		DATA REV			COD. 20002773	



DISEGNO CIRCUITO VISTA LATO SALDATURE						
DES.: SCHEDA TASTIERA AR 2100 ADV					et medical devices	
LAYER N° 2						
FILE NAME TAS_2100_ADV_2PCB						
PCB REFERENCE 2PCB16001812					CAVARENO (TN)-ITALY	all rights reserved
DRAWER	CHECK	DATA 15.11.2002			SHEET 4 OF 5	SCALA 1 : 1
GS		DATA REV			COD. 20002773	

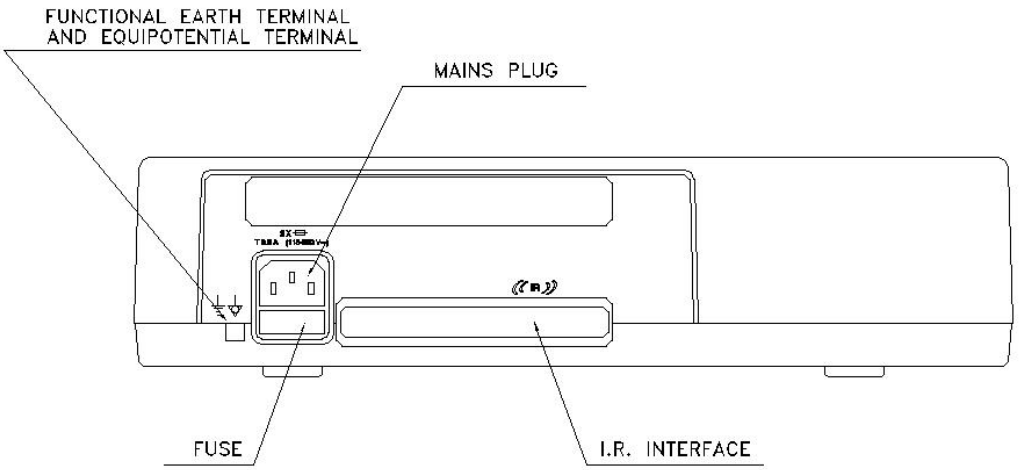
T1

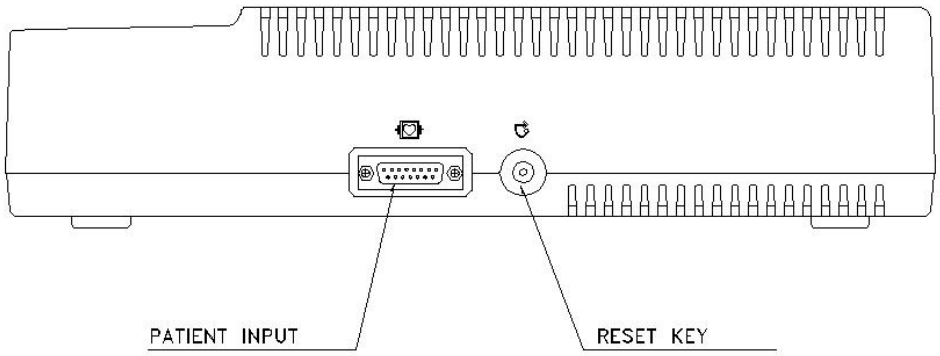
TOP VIEW



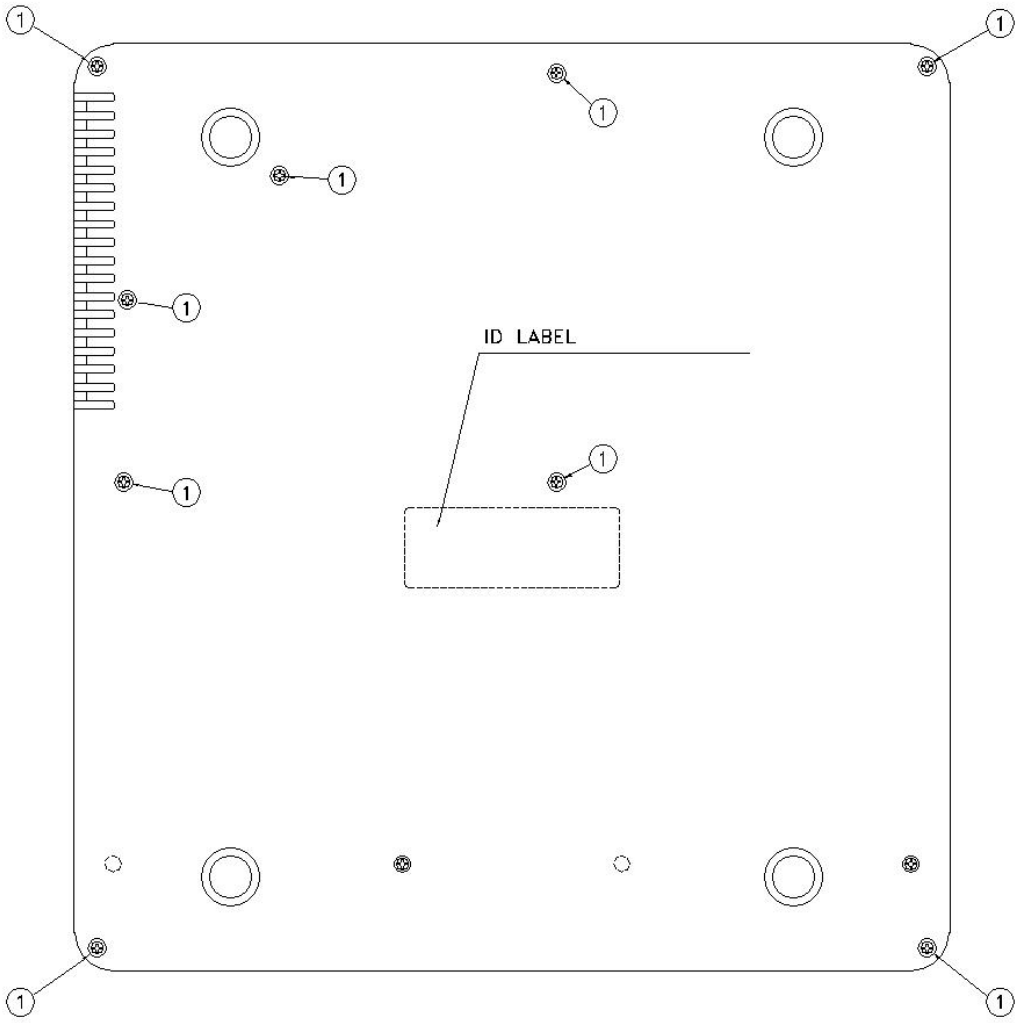
1. PRINTER FIXING SCREWS
2. PAPER COMPARTMENT LID FIXING
3. KEYBOARD MEMBRANE

SIDE VIEWS


FUNCTIONAL EARTH TERMINAL
AND EQUIPOTENTIAL TERMINAL
MAINS PLUG
FUSE
I.R. INTERFACE

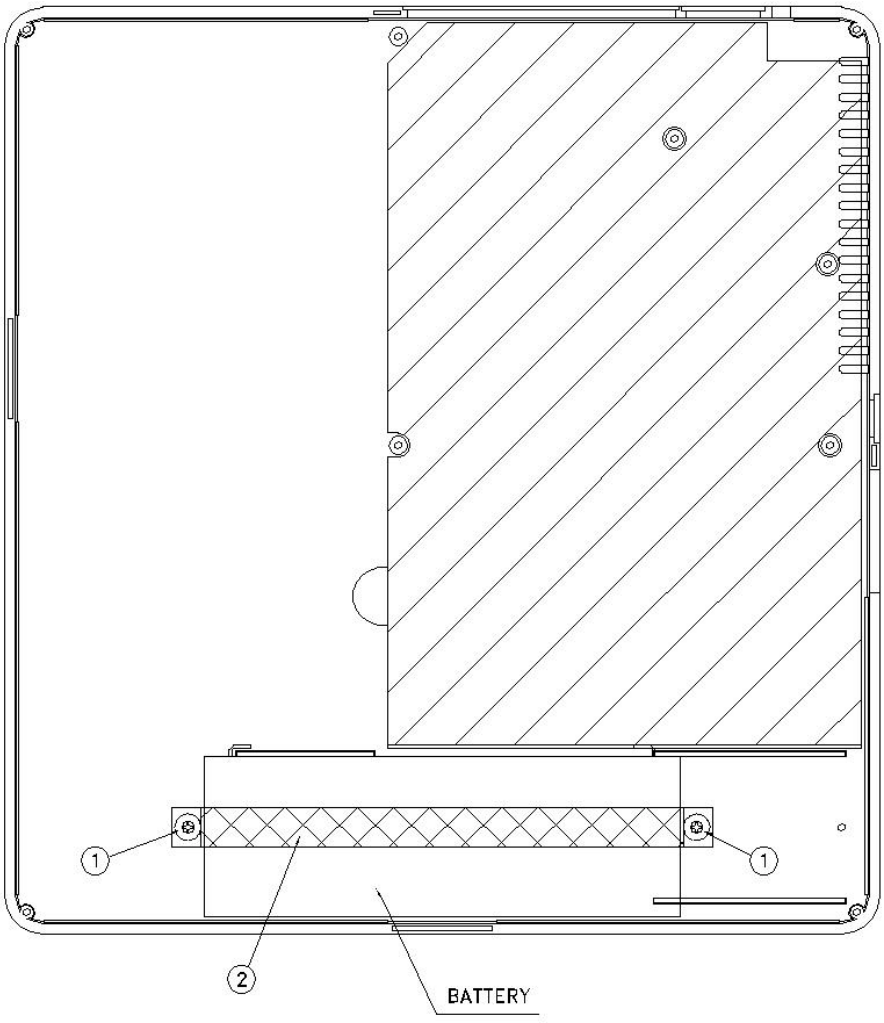

PATIENT INPUT
RESET KEY

BOTTOM VIEW



(1) MOTHER BOARD AND LOWER HOUSING FIXING SCREWS

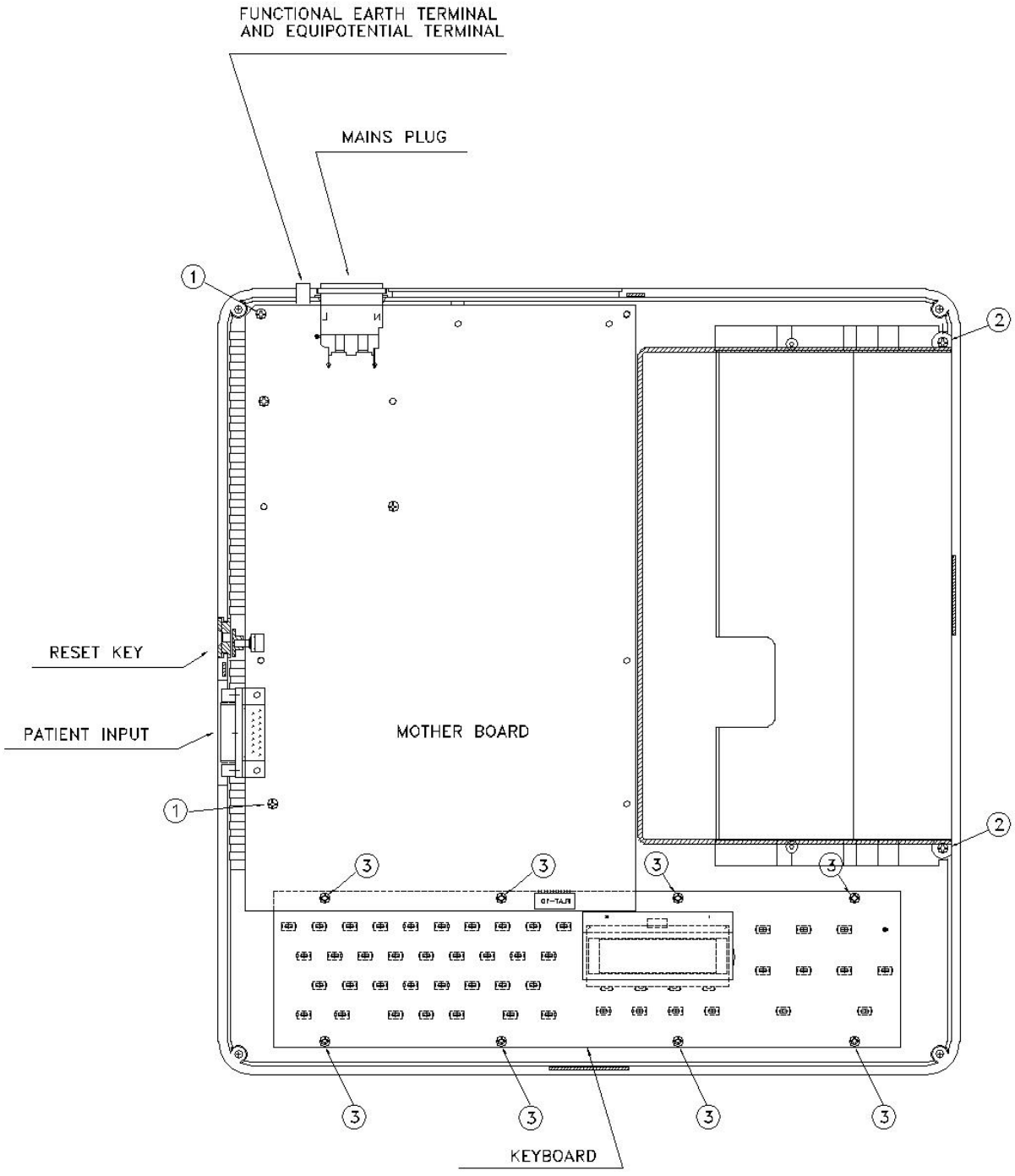
LOWER HOUSING



(1) BATTERY BRACKET FIXING SCREWS

(2) BATTERY BRACKET

UPPER HOUSING

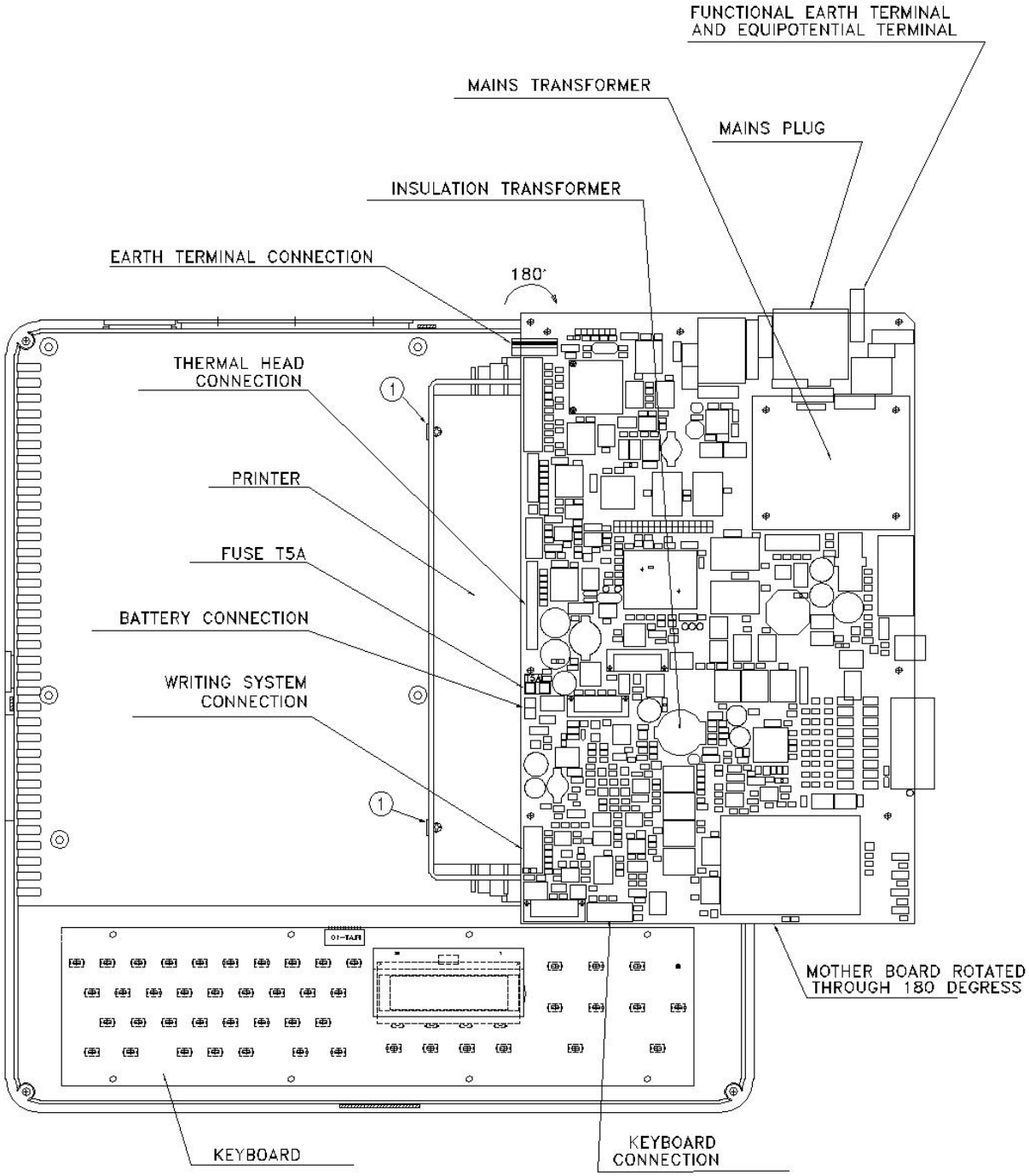


(1) MOTHER BOARD FIXING SCREW

(2) CLUTCH PAPER COMPARTMENT LID FIXING SCREWS

(3) KEYBOARD FIXING SCREW

UPPER HOUSING

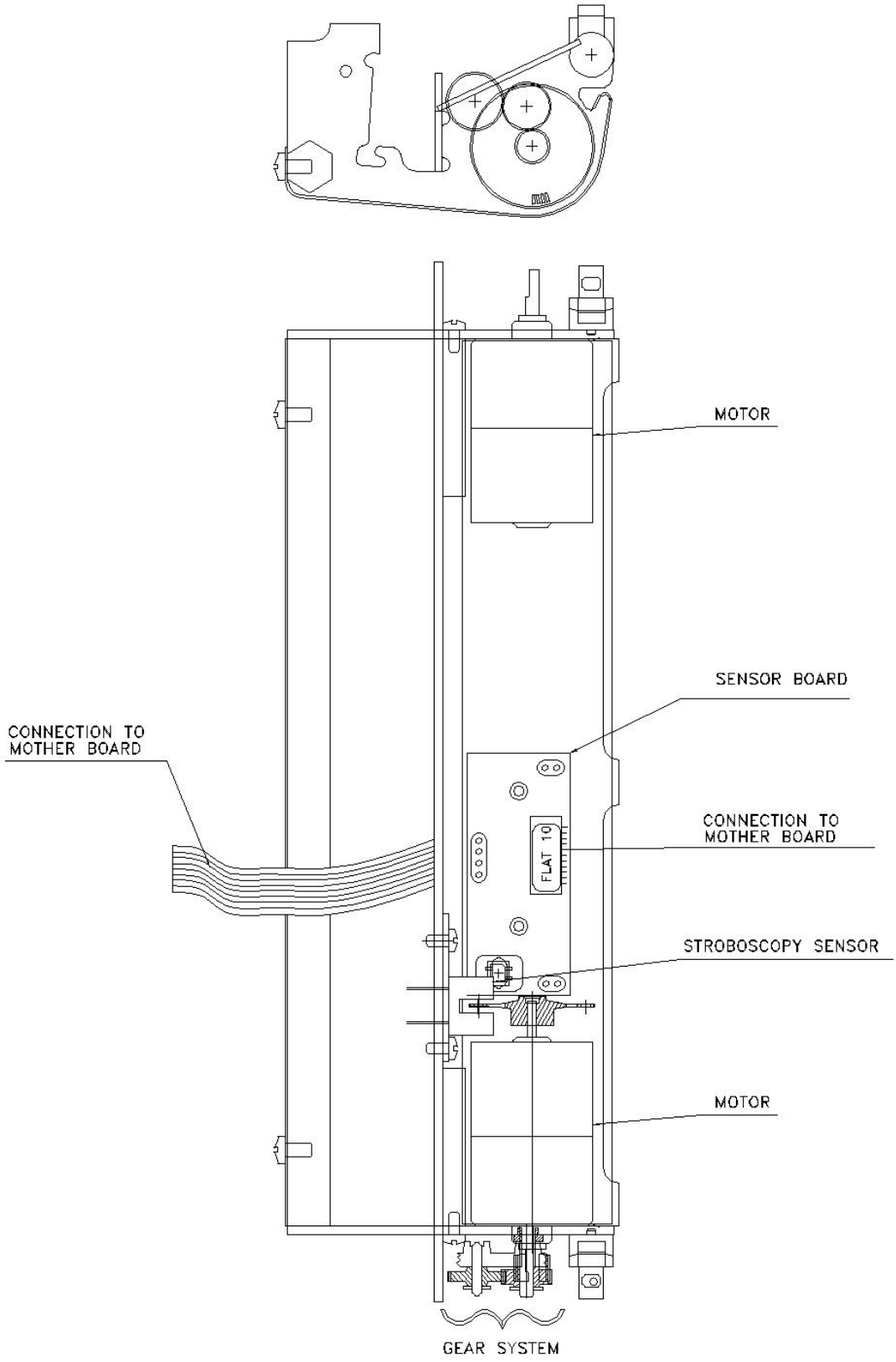


(1) PRINTER FIXING SCREWS

et medical devices

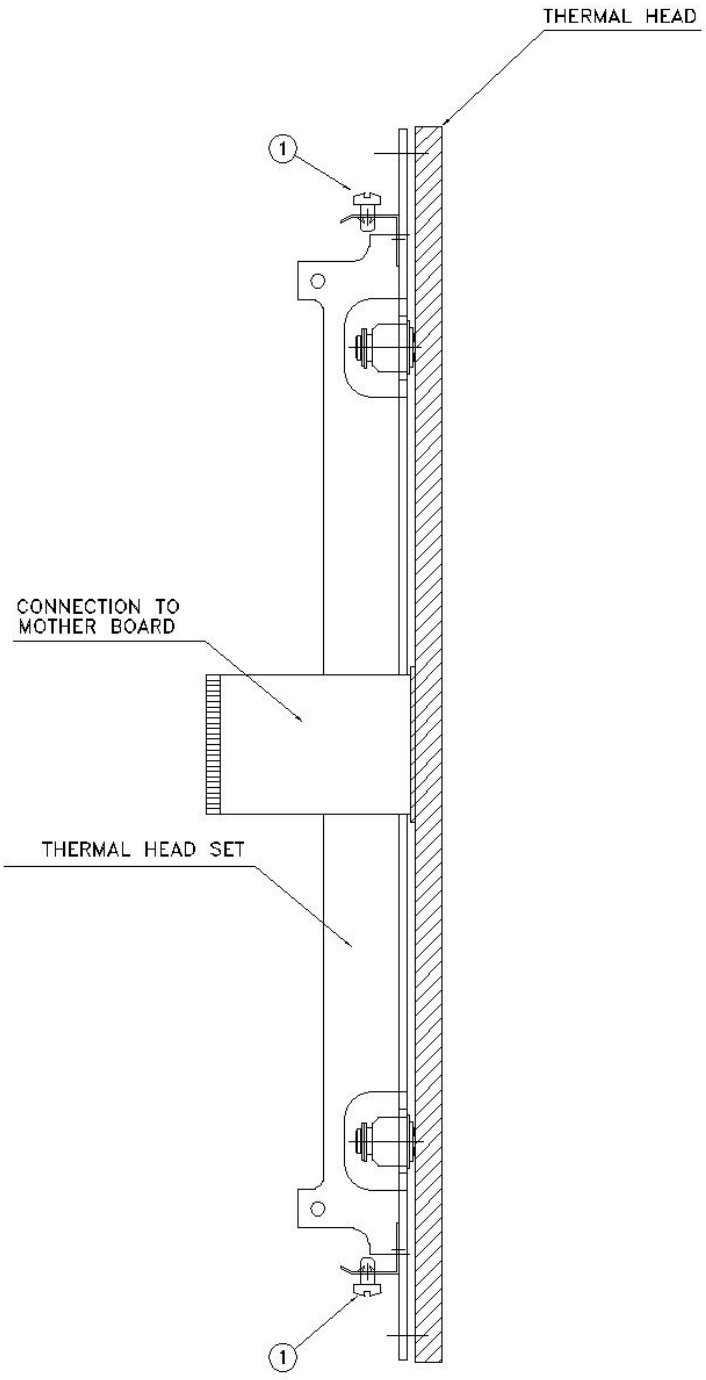
WRITING SYSTEM

T7A

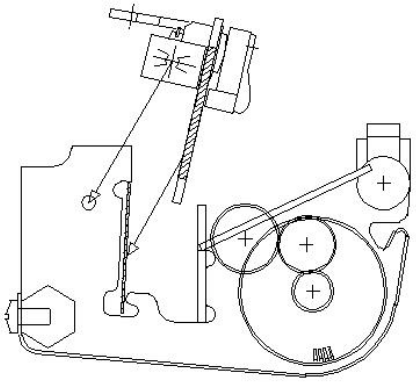


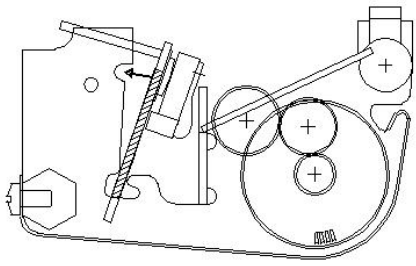
T7B

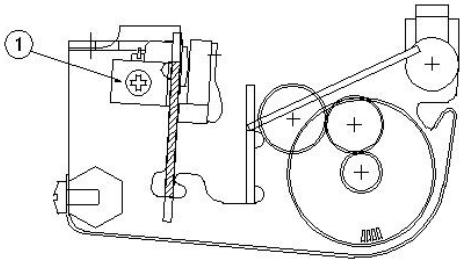
PRINT HEAD ASSEMBLY



MOUNTING WRITING SYSTEM

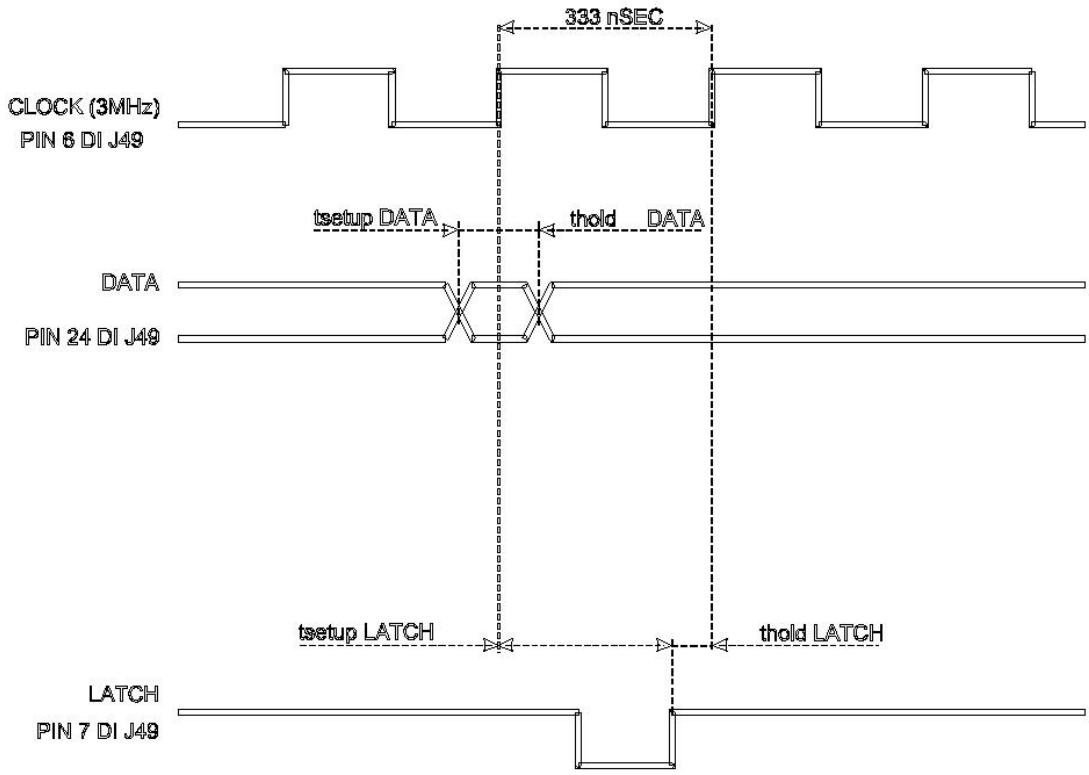


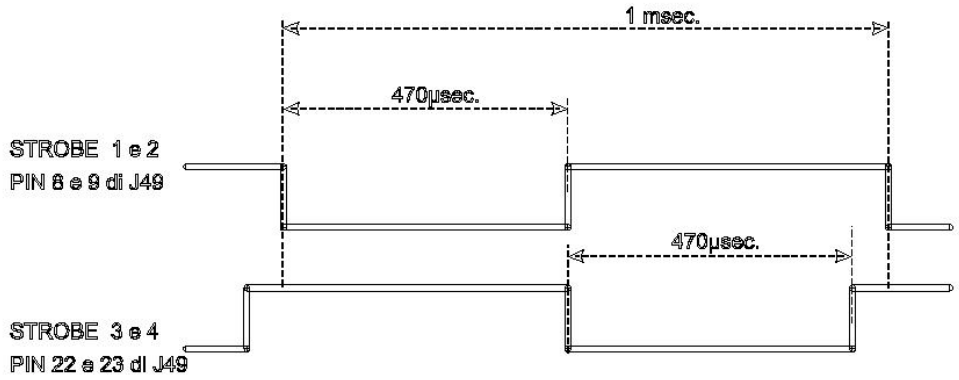




(1) PRINTER FIXING SCREWS

THERMAL HEAD TEST POINT
210 mm





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thold DATA= min 50 nsec.
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thold LATCH = min 50 nsec.

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