CardioSmart/CardioSmart ST Servicing Instructions

Version 1.2 and 1.3 227 435 11 SA(e) Revision D



marquette

A GE Medical Systems Company

Caution:

During repairs/service interventions, observe the protective measures against damage due to ESD.

- * Marquette Hellige GmbH considers itself responsible for the effects on safety, reliability, and performance of the equipment, only if:
 - assembly operations, extensions, readjustments, modifications, or repairs are carried out by Marquette Hellige GmbH or by persons authorized by Marquette Hellige GmbH,
 - the electrical installation of the relevant room complies with the applicable national and local requirements, and
 - the instrument is used in accordance with the instructions for use.
- * This manual contains service information; operating instructions are provided in the user manual of the instrument.
- * This manual is in conformity with the instrument at printing date.
- * All rights are reserved for instruments, circuits, techniques, and names appearing in the manual.

[©] Marquette Hellige GmbH Printed in Germany Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 3

227 435 11 D

Contents

1. Device	. 6
1.1 Block circuit diagram of entire instrument	
1.2 Mechanical Components	
2. Functional description	11
2.1 PCB Power Supply_CS	
2.1.1 Switch on/off circuit	
2.1.2 Charging circuit for NC Battery	11
2.1.3 Device behavoir depending on the state of battery charge	12
2.2 PCB Control CS_S	
2.2.1 Generation of the logic power supply +5V	
2.2.2 ECG recording and front-end processing	
2.2.3 Controller core	
2.2.4 Real-time clock	
2.2.5 Memory	
2.2.6 Printhead control	
2.2.7 Motor controller	
2.2.8 RS-232 interface	
2.2.9 Keypad interface	
2.3 PCB Graphics Display_CS	
2.3.1 Power supply	
2.3.2 Background illumination	
2.3.2 Background multimation	
2.3.5 Contrast control	
2.4 memai menaces	
2.4.2 Electronic interfaces	
2.4.2.1 Interface Character Display	19
2.4.2.2 Interface Graphics Display	21
2.4.2.3 Interface PCB Power Supply_CS	
2.4.2.4 Option interfaces	
2.5 Interfaces to peripherals	
2.5.1 Electronic interfaces	
2.5.1.1 RS-232 interface	
2.5.1.2 Patient input	
2.6 Limitations	27
3. System test functions	30
3.1 System test functions with graphics display	
3.1.1. General information	
3.1.2 Test start	
3.1.3 Display test (1)	
3.1.4 Key test (2)	
3.1.5 Motor test (3)	
3.1.6 Test results (4)	33
3.1.7 Self-test	34
3.1.8 Recording test (5)	
3.1.9 Interface test (6)	
3.1.10 Time and date (7)	36
3.1.11 Electrode test (8)	
3.1.12 Test time constants (9)	38
3.1.13 Setting the Device model (V)	

Marquette Hellige GmbHCardioSmart/CardioSmart ST V 1.2/ V 1.3Page 4227 435 11 D

	3.1.14 Switching over the program for Interpretation (C)	40
	3.2 Device test functions with character display	42
	3.2.1 General information	42
	3.2.2 Test start	42
	3.2.3 Display test (1)	42
	3.2.4 Key test (2)	43
	3.2.5 Motor test (3) 3.2.6 Test results (4)	43 44
	3.2.6 Test results (4)	44 45
	3.2.7 Self-lest	45 45
	3.2.9 Interface test (6)	40
	3.2.10 Time and date (7)	47
	3.2.11 Electrode test (8)	48
	3.2.12 Test time constants (9)	49
	3.2.13 Setting the Device model (V)	49
	3.2.14 Switching over the program for Interpretation (C)	51
4.	Repair instructions	52
	4.1. Safety instructions	52
	4.2 Replacing components	52
5.	Troubleshooting tips	56
_		
6.	Adjustment instructions	59
7	Somioing and maintenance	61
1.	Servicing and maintenance 7.1 Technical inspection	61
	7.1.1 Visual check	61
	7.1.2 Test functions	62
	7.1.2.1 Recommended testing instruments and accessories	62
	7.1.2.2 Test preparations	62
	7.1.2.3 Operating and display unit performance tests	62
	7.1.2.4 Test for recording speeds 25 and 50 mm/s	63
	7.1.2.5 Device test result check	63
	7.1.2.6 RS232 interface test	63
	7.1.2.7 Analysis of the ECG signals and HR value	63
	7.1.2.8 Pacemaker identification test	64
	7.1.2.9 Identification of disconnected electrodes	65
	7.1.2.10 Checking the charge status of the NC battery	65
	7.1.2.11 Pump leakage	65
	7.1.3 Safety Analysis Tests	66
	7.1.3.1 General information	66
	7.1.3.2 Protective Earth Resistance Test	66
	7.1.3.3 Measurement of Leakage Current	66
	7.1.3.3.1 Enclosure Leakage Current Test	67
	7.1.3.3.2 Patient Leakage Current Test	68
	7.2 Maintenance, cleaning, disinfection	. 69
8	Parts Lists	70
0.		10
9.	Specifications	73
	9.1 Specifications CardioSmart	73
	9.2 Specifications CardioSmart ST	79
		-

Marquette Hellige GmbHCardioSmart/CardioSmart ST V 1.2/ V 1.3Page 5227 435 11 D

10. Device documents	85
Annexe	86

Revision History

- V 1.0 May 1995 Initial Release
- V 1.1 March 1996 Update 1
- V 1.2 February 1997 Update 2
- V 1.2/1.3 August 1997 Update 3

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 7 227 435 11 D

1. Device description

This Service Manual for device versions V1.2 and V1.3 describes both CardioSmart and CardioSmart ST. Unless indicated specifically, the description applies to both CardioSmart and CardioSmart ST.

The device version V1.3 hardware components are identical to those of device version V1.2. The new combinations of these components in V1.3 result in new models, so-called regional models. Differences between device versions V1.2 and V1.3 are indicated clearly in the relevant sections.

The CardioSmart is a portable electrocardiograph with an integrated printing unit. It is used to acquire, record and process ECG signals.

It is designed for line-power and battery operation. Operation without a battery is not possible. Power supply unit and battery are integrated into the instrument.

CardioSmart ST has an additional ergometry mode option with its own ergometry keypad.

The patient cable for the acquisition of ECG signals is connected by means of a 15pin connector as used in earlier ECG recorders. This means that the patient cables used in the past can still be used.

Stored patient data and ECGs can be transmitted to a PC via an RS-232 interface. This requires a CardioProm version with additional patient data memory.

CardioSmart and CardioSmart ST are both based on the same hardware platform V1.2 or V1.3 and represent different types of the basic unit 101 116 xx.

With device version V1.2, the following models are available:

101 116 01	CardioSmart international	230V~	
101 116 02	CardioSmart US Version	115V~	
101 116 03	CardioSmart Russian	230V~	
101 116 04	CardioSmart international	230V~ with	integrated pump
101 116 05	CardioSmart Russian	230V~ with	integrated pump
101 110 10		0001/	
	CardioSmart ST international		
101 116 11	CardioSmart ST international	230V~	with integrated pump
101 116 12	CardioSmart ST US Version	115V~	
101 116 13	CardioSmart ST US Version	115V~	with integrated pump
With device ver	sion V1.3, the following mode	ls are additio	naly available.
	-		
101 116 06	CardioSmart EUROPE 2	230V~	
101 116 07	CardioSmart EUROPE 2	230V~	with integrated pump

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 8 227 435 11 D

101 116 15 101 116 16 101 116 17 101 116 18	CardioSmart ST Russian CardioSmart ST Russian CardioSmart ST EUROPE 2 CardioSmart ST EUROPE 2 CardioSmart ST ASIA	230V~ 230V~ with integrated pump 230V~ 230V~ with integrated pump 115V/230V~ 115V/230V~
101 116 19	CardioSmart ST ASIA	115V/230V~ with integrated pump

The CardioSmart entire instrument comprises the following components:

- CardioSmart Basic Instrument, without display and CardioProm
- CardioProm Storage Module, there are several modules with different features, with or without ECG storage facility
- CardioVision Display, there are 2 different displays available:
 - CardioVision Text, LCD module 2-line
 - CardioVision Graphics, graphics LCD

The CardioSmart ST entire instrument comprises the following components:

- CardioSmart ST Basic Instrument, without display and CardioProm
- CardioProm ST Storage Module, there are several modules with different features, with or without ECG storage facility
- CardioVision Graphics, graphics LCD

CardioSmart ST is not enabled for CardioVision Text

This concept permits the user to configure an instrument himself to meet his own application specifications. It is also possible to upgrade the basic version.

The hardware comprises the following functional blocks:

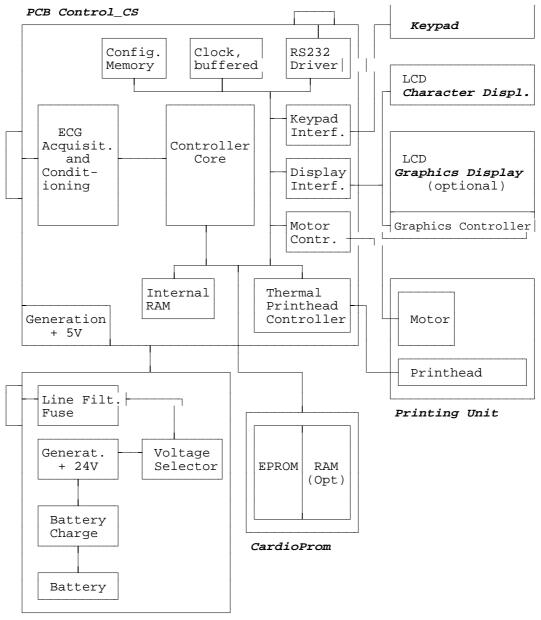
- PCB Control CS S (basic instrument)
- Power supply unit with battery (basic instrument)
- Keypad (basic instrument) -- Printing unit
 - (basic instrument)
- PCB Energy Storage_CS
- (storage module)
- Display (character or graphics display)

The following functional blocks are constructed directly as PCBs:

- PCB Control_CS
- PCB Energy Storage CS
- PCB Power Supply CS with battery charging circuit
- PCB Graphics Display_CS

The applications, functions and operation of the CardioSmart are described in the User's Manual.

1.1 Block circuit diagram of entire instrument



Power Supply Unit

1.2 Mechanical Components

The main mechanical components comprise the **upper and lower shell** of the **CardioSmart Basic Instrument**. The lower shell serves as a basic unit to receive the following assemblies:

- Mains input module with instrument On/Off switch
- PCB Power Supply_CS
- Battery
- Thermal printing unit
- Paper container
- PCB Control_CS

The upper shell accommodates the keypad, which is connected to the PCB Control_CS via a 22-pin connector. The display (character or graphics display) is also integrated into the upper shell.

The **CardioProm** (program module) also has its own housing, comprising an upper and lower assembly section. It contains the PCB Energy Storage_CS, which is connected to the PCB Control_CS via a multipoint connector when inserted into the CardioProm slot.

The two available **displays** are also located in a housing, comprising an upper and lower shell. The graphics display contains the graphics LC display itself, as well as the associated control electronics, it can be swivelled within the range from 0° to 45° with 5 lock-in positions. The character display only contains the character LCD and cannot be swivelled. The two displays can be connected to the PCB Control_ CS by insertion into the depression in the upper shell of the basic instrument provided with a female multipoint connector.

The 15-pin input connector to **connect the patient cable** and the 9-pin connector for the **RS-232 interface** are located directly on the PCB Control_CS.

Models 101 116 04/05 have an added integrated suction pump, comprising the pump module 303 442 91 and the PCB Pump 388 029 18.

2. Functional description

The block circuit diagram of the entire instrument in Section 1.1 and the functional blocks of the P-plans describe the individual functional blocks.

2.1 PCB Power Supply_CS

The PCB Power Supply provides the following functions:

- Secondary clock-rated power supply unit to generate the fundamental device voltage UVERS
- Device switch on/off circuit
- Charging circuit for NC battery
- Battery almost empty identification
- Battery empty instrument switch-off

2.1.1 Switch on/off circuit

The device on/off switch (momentary toggle switch) supplies the starting pulse. The actual stop signal comes from the PCB Control_CS via the DOFF cable.

In the line-power operating mode CardioSmart can be switched off by:

- Device on/off switch
- Processor (DOFF)

In the battery operating mode CardioSmart can be switched off by:

- Device on/off switch
- Processor (DOFF)
- Battery empty identification

In the line-power operating mode recording can be switched off by:

- Battery empty identification

2.1.2 Charging circuit for NC Battery

A charging IC is used to charge the battery. During charging it monitors the battery voltage function and switches over from rapid charging to trickle charging in conformity with the charging current.

The charging circuit is activated by applying the power supply voltage or battery. If a recording is made whilst the device is in the operating mode the charging circuit is deactivated.

2.1.3 Device behavoir depending on the state of battery charge

As a general rule the following applies:

No applied line-power voltage:

Operation of the device without a battery is not possible

Applied line-power voltage, battery is charged:

Device completely operational

Applied line-power voltage, battery **depleted**:

Device is only partially operational (everything except recording) Battery charging is triggered by:

Application of line-power voltage

Switching off a current recording, manually with the Stop key or automatically when the cutoff voltage has been attained

Device behavoir:

- State 1 Battery depleted, power supply system is connected up: Battery charged in accelerated mode; when full, switchover to conservation charging, no time limit
- State 2 Battery full, power supply system is connected up: Battery charged in accelerated mode; when full, switchover to conservation charging, no time limit
- State 3 Battery depleted, no line-power supply, device is switched on: Device inoperative
- State 4 Battery full, no line-power supply, device is switched on: Device fully operative, when battery almost empty message appears LEDBAT signal activated, when battery empty message appears the device becomes inoperative
- State 5 Battery depleted, power system supply is connected, charging begins, device is switched on:
 All functions except recording, as long as the battery cannot supply the printhead with sufficient power.
- State 6 Battery full, power supply system is connected, device switched on: Device fully operative. During recording charging is interrupted, at stop recharging begins until the charging IC switches to conservation charging.

2.2 PCB Control CS_S

2.2.1 Generation of the logic power supply +5V

The logic power supply +5V is generated directly on the PCB Control_CS. The stabilized voltage UVERS, which is generated by the PCB Power Supply_CS, serves as the input voltage.

The +5V power supply is generated by the clock-rated **voltage controller**. The **"adjustable version"** of the controller is used in order to be able to use it later for applications requiring other voltages, the output voltage is determined by appropriate dimensioning of the voltage divider at the feedback input of the voltage controller.

2.2.2 ECG recording and front-end processing

The main element of this operational unit is a **set of chips comprising 4 ASICs** located on the PCB.

The **patient lead** is connected with a **15-pin connector**. Overvoltage arresters at the electrode inputs provide high-voltage protection. A hybrid chip acts as a microfuse for each electrode, it serves to identify a disconnected electrode.

The patient input is classified as cardiac floating and is defibrillation-proof.

Each electrode input is preamplified after the hybrid chip with a low-noise operational amplifier with a small input voltage, before it is fed into the two ASICs with the sigmadelta resistors.

The filter time constants can be adjusted by the controller core by a command. 8 time constants are available for selection (system test).

N common-mode compensation ensures suppression of interference, at the same time serving to improve the in-phase suppression of the input electrodes.

To protect patients the ECG recorder and conditioning processor are assembled as floating components. Digital signals from and to the controller core are transmitted via optoelectronic couplers, the floating power supply +/-5V is generated by a flyback converter from the logic power supply +5V.

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 14 227 435 11 D

2.2.3 Controller core

The actual core comprises the **Motorola Controller 68332**, containing the following integrated components:

- CPU32, computer core, internal 32-bit register, external 16-bit processor
- TPU, an independently operative clock generator processor
- QSM with SCI to implement a simple RS-232 interface and a serial QSPI interface with up to 16 channels
- SIM with chipselect generation, system monitoring, clock synthesizer

The **watchdog/reset generation** is implemented with an integrated system monitoring chip. It has the following functions:

- Power-up reset for the 68332 when the instrument is switched on
- Voltage monitoring with reset generation
- Watchdog function
- Switchover to battery for buffered RAMs
- Access protection for buffered RAMs

2.2.4 Real-time clock

This provides the time of day and date. When the device is operative it is powered by the logic power supply, when the device is switched off a 3-V lithium cell is switched in to keep the clock running.

The control signals for the clock (chipselect read/write signal) are generated in the **PAL RTC_Control**, which also contains the release sequence for the character display.

2.2.5 Memory

Static RAMs are used as **RAM memory** with an internal organization 128kbit x 8. They are equipped with 4 chips, providing an organisation of 256kbit x 16. It is possible to add 4 further chips to give a RAM memory area of 1MByte. The access time is 70 ns, i.e., access **without wait states**.

2.2.6 Printhead control

The printhead controller takes on the complete control of a 216-mm thermal printhead with a line width of 200 mm. It also contains the printhead monitor, which reduces the heating time with increasing printhead temperature, terminating the printhead power supply when the printhead temperature reaches 55°C. The printhead power supply is reactivated only when the printhead temperature drops below 50°C.

The core is a **gate array**, which takes on the heating time management for each dot. The speed-dependent heating parameters are transmitted serially.

For the **printhead monitoring** the temperature of the thermal array printhead is measured by a thermistor located on the printhead. A constant current source effects a temperature-dependent voltage drop at a comparator input, the switching threshold being adjusted by hysteresis at the other comparator input. If a printhead temperature of 55°C is exceeded, the message PRINTHEADTEMP is activated and the current supply to the printhead prevented by the STROBE signal. Only after the temperature drops below 50°C is the PRINTHEADTEMP message disabled and the current supply via STROBE reenabled.

A second comparator generates a VTEMP signal when the temperature reaches 45°C, it is disabled again when the temperature drops below 40°C. It represents a prewarning signal, so that the quantity of data at the printhead is reduced to prevent it being switched off.

In addition, a continuous reduction in the current activation time occurs with increasing temperature, resulting in a regular type face throughout the entire temperature range.

The **printhead is operated directly at the battery**, i.e., the printhead voltage is dependent on the state of battery charge. Compensation is achieved by reducing or extending the printhead current activation time accordingly, ensuring that the type face is maintained within the fluctuation range of the battery voltage.

2.2.7 Motor controller

This activates the CardioSmart's DC motor. This motor does not have a speedo, control is achieved according to the principle of current compensation.

The main components are the speed selector, motor controller, and motor current monitoring.

The resistor for the **control** according to the principle of current compensation is attached directly to the motor casing.

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 16 227 435 11 D

The voltage of +/- 12 V required to send control signals is generated from the supply voltage as follows: An in-phase regulator generates + 12 V, due to the small current requirements the voltage -12 V is generated by an inverting voltage pump. The supply voltage +/-12 V is also used for the temperature monitoring system of the printhead controller.

It is only enabled during printing!

When the motor current is raised > 140 mA (e.g., as a result of paper jam, transmission problems) the **motor current monitoring system** terminates paper transport and the message "Please insert paper and press return key" appears on the display.

2.2.8 RS-232 interface

The CardioSmart has an RS-232 interface which, except for the RS-232 driver chip, is directly integrated into the controller.

It has the following attributes:

- Software handshake with XON/XOFF
- No HW handshake
- Transmission speed 1200 19200 Baud

To achieve **protection against ESD up to 10kV**, the interface is equipped with additional suppressor diodes.

2.2.9 Keypad interface

The interface to the keypad is via the **22-pin connector AS**. The keypad itself is a membrane keypad with touch-sensitive check-back.

The keypad comprises a matrix with 7 columns and 7 rows.

The CardioSmart ST keypad has additional keys for ergometer/treadmill control. Depending on the keypad used (CardioSmart or CardioSmart ST) the PC receives a corresponding signal, identifying the device used.

Identification of the key pressed is as follows:

The controller activates a column, activation is via low-level, simultaneously it reads out the register for the lines and by a low-level signal identifies whether one or more keys had been pressed. Then the next column is activated. The run procedures are repeated automatically until all columns have been activated.

In addition, the LEDs for start and stop, for the power supply system display and the battery status control are located directly on the keypad.

2.3 PCB Graphics Display_CS

This PCB is only used in connection with the component parts of the CardioSmart graphics display unit. It comprises the following functional units:

- Voltage generation
- CPU interface, display control
- Background illumination
- Contrast control

2.3.1 Power supply

A **negative voltage of -23 V** is required for the power supply of the display. It is generated by an inverting switching controller from the 5-V power supply. The output voltage -23 V is enabled by the additional external wiring of the switching controller. The voltage -23 V also serves as a voltage source for the generation of the **negative contrast voltage**.

The **functional unit LCD BLOCK** ensures that the logic power supply +5 V is active at the graphics display before the negative power supply and the contrast voltage. When the instrument is switched off the negative power supply and the contrast voltage are switched off first.

2.3.2 Background illumination

The background illumination of the graphics display is effected by a **CFL tube**, which requires an alternating voltage of approx. 800 Vss.

The alternating voltage is generated by a voltage inverter, driven by 5 V. Since the CardioSmart is a portable, battery-operated device, the background illumination can be **enabled and disabled** (configuration).

2.3.3 Contrast control

The contrast control has an additional **temperature compensation control.** However, when there are rapid fluctuations in temperature it takes a certain time until the compensation is complete, since the display itself has a greater thermal time constant.

2.4 Internal interfaces

2.4.1 Mechanical interfaces

The 3 following mechanical interfaces are important within the CardioSmart:

- Interface to CardioProm
- Interface to display CardioVision Text
- Interface to display CardioVision Graphics

Interface to CardioProm

The CardioProm has its own housing, which is conducting to prevent damage by ESD. To shunt any possible static charge it has 3 rails on the underside which, on the PCB Control_CS in the CardioSmart basic device, when inserted make contact with the 3 rails on GND, thereby shunting the charge.

This mechanical insertion of the rails ensures that a fail-safe contact is made with the PCB Control_CS.

Furthermore, mechanical coding ensures that the non-compatible CardioProms of the EK56/EK512 series cannot be inserted into the slot. Similarly, the insertion of CardioSmart CardioProms into the EK56/512 slot is not possible.

Interface to display CardioVision Text

The display CardioVision Text is placed into the depression provided in the upper shell of the CardioSmart basic device. The mechanical rail on the outside of the display ensures the electrical contact is automatic and fail-safe. The display CardioVision Text can be replaced, e.g., by a CardioVision Graphics using the appropriate tools without opening the device.

Interface to display CardioVision Graphics

The display CardioVision Graphics is also placed in the above-mentioned depression, the mechanical rail on the outside also ensures a fail-safe contact. In contrast to the CardioVision Text, the CardioVision Graphics can only be replaced by opening the upper shell of the basic device.

2.4.2 Electronic interfaces

This section describes the pinning, function and significance of the signals of the internal interfaces of the functional components.

2.4.2.1 Interface Character Display

The interface to the character display provides all the signals to connect the display CardioVision Text. It comprises the upper 8 bits of the data bus, control signals and the signal for the contrast control.

Connection denotation: AG/

Female multipoint connector **2 x 7-pin**, **upright** (180 °), reverse terminal protection achieved mechanically.

The function of the individual pins is given in the following table. The definition as an Input/Output is seen with reference to PCB Control_CS.

Pin Num- ber	Input/Out- put	Denotation	Function
1	Output	GND	System ground
2	Output	+ 5 V	Voltage supply
3	Output	CHAR_CONTR 0 5V	Contrast character display
4	Output	AD_12	Controller address bus bit 12
5	Output	RW_	Read/write signal
6	Output	ENCHARD	Enable character display
7	Bi-Direct, tristate	DB_8	Controller data bus bit 8
8	Bi-Direct, tristate	DB_9	Controller data bus bit 9
9	Bi-Direct, tristate	DB_10	Controller data bus bit 10

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 20 227 435 11 D

Te			
10	Bi-Direct, tristate	DB_11	Controller data bus bit 11
11	Bi-Direct, tristate	DB_12	Controller data bus bit 12
12	Bi-Direct, tristate	DB_13	Controller data bus bit 13
13	Bi-Direct, tristate	DB_14	Controller data bus bit 14
14	Bi-Direct, tristate	DB_15	Controller data bus bit 15

2.4.2.2 Interface Graphics Display

The interface to the graphics display provides all the signals to connect the display CardioVision Graphics. It comprises the upper 8 bits of the data bus, address bus, control signals and the signal for the contrast control.

Connector denotation: AH/

2.4.2.3 Interface PCB Power Supply_CS

This has the voltages from the power supply unit to generate the + 5 V and the other voltages, the control of the LEDs for the power lamp and battery monitoring, the control signals for battery charging and switching on the printhead and motor power supply as well as the signal to switch off the device on the controller's part.

Connector denotation: AE/

Male multipoint connector **2 x 10-pin, upright** (180 °), reverse terminal protection and coding with coding pin 12.

The function of the individual pins is given in the following table. The definition as an Input/Output is seen with reference to PCB Control_CS.

Marquette Hellige GmbHCardioSmart/CardioSmart ST V 1.2/ V 1.3Page 21227 435 11 D

Pin Num- ber	Input/Out- put	Denotation	Function
1	Input	LEDLIN	Control of LED for power supply system "-" = mains not connected "AC" = mains connected
2	Output	REG_ON	Printhead power supply, motor enabled by controller: "0" = Enable battery charging "1" = Enable printhead power supply
3	Output	GOFF_	Switch on device with controller "0" = Device off "1" = Device on
4, 5	Input	UVERS	Input voltage to generate +5 V
6	Output	+ 5 V	Logic power supply
7,8,9, 10	Input	COMMON_IN	Input voltage to generate motor- printhead voltage and +/- 12V
11	Input	REG_OFF	Printhead power supply, motor enabled by power-supply unit: "0" = Enable battery charging "1" = Enable printhead power supply
12		CODE	Coding pin
13, 14, 15, 16	Input	GND	System ground
17	Input	VRAM	Buffered voltage to generate the RAM standby power supply
18	Output	COMMON_S	Voltage switched in from COMMON_IN
19		NC	NC
20	Input	LEDBAT	Charging status display for BATTERY: "0" = battery needs charging "1" = battery charged, normal operat.

2.4.2.4 Option interfaces

Option Power Check

This constitutes a service connector to enable checking of all the voltages active within the system. This **is not an extension port**, the voltages must not be used to supply power to other components!

Connector denotation: AF/

Male multipoint connector 1 x 6-pin, upright (180 °), for servicing purposes only!

The function of the individual pins is given in the following table. The definition as an Input/Output is seen with reference to PCB Control_CS.

Pin Num- ber	Input/Out- put	Denotation	Function
1	Output	+ 12 V	Testing point power supply + 12 V
2	Output	GND	System ground
3	Output	- 12 V	Testing point power supply - 12 V
4	Output	COMMON_S	Testing point power supply motor voltage
5	Output	GND	System ground
6	Output	+ 5 V	Testing point logic power supply + 5 V

2.5 Interfaces to peripherals

The CardioSmart has only 3 interfaces for peripherals:

- Mains input
- Patient Input
- RS-232 interface

The **mains input** interface on the device is a 3-pin standard cold appliance socket connection, which is integrated into the mains input module. Connection to the mains is effected via a 3-pin power cord with a non-fused earth conductor.

Although the mains input is not designed as a "wide range input", adjustment to the two mains voltage ranges $110V \sim ... 120V \sim and 220V \sim ... 240V \sim$ is easily achieved without having to open the device or a wiring change of the bridges:

- Check voltage setting in the inspection window of the interrupter of the mains input module
- If the voltage value is not the same as the mains voltage:
- Disconnect mains plug!
- Open interrupter with appropriate tool
- Take out fuse holder with fuses
- Insert fuses rated according to the rating plate specifications
- Reinsert holder so that the required voltage is visible
- Close interrupter
- The required mains voltage should now appear in the inspection window

This readjustment is to be carried out by the manufacturer or servicing agent only!

No further description of the mechanical and electronic parameters of the mains input is given in Section 2.5.

The mechanics and the interface configuration as used in the EK53/EK56 and in the EK512 are implemented in the **patient input**. This means that all the patient cables used up to date can still be used, this also being true for the suction system with its integrated pump.

A 9-pin sub-D connector with a standard configuration of the signals TXD, RXD and GND is implemented in the construction of the **RS-232 interface**. In addition, it is attached to the connected plug housing by means of threaded inserts. The EK53/56 and EK 512 RS-232 power cables can thus no longer be used.

The cable 223 362 03 is used as an RS-232 cable to the PC.

2.5.1 Electronic interfaces

2.5.1.1 RS-232 interface

This comprises the transmitter signal TXD, the incoming signal RXD and the reference ground GND. The pin configuration is the same as that used for a standard PC 9-pin sub-D socket. The interface does not operate with a hardware handshake.

Furthermore, a REMOTE START input is provided at pin 8.

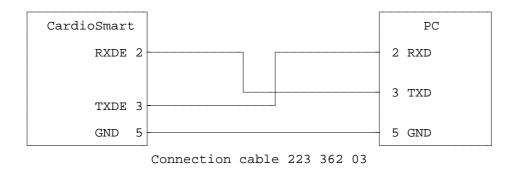
Transmission is in accordance with the standard V-24 protocol, input and output voltages are defined as follows:

- maximum input voltage at RXD: +/- 15V
- minimum output voltage at TXD: +/- 5 V
- additional input protection against ESD effects: +/- 10kV

In addition, there is a REMOTE START input at pin 8 with the following specifications:

- external short-circuiting contact via circuit reference referred to ground
- max. source resistor switch: $R_i < 300 \Omega$
- make time >100 ms
- continuous load limits +/-10 V
- ESD protection to max. +/-10 kV

Connection principle to PC



The connector is denoted: AC/

Male multipoint connector sub-D socket housing, 9-pin, 90° offset

Marquette Hellige GmbHCardioSmart/CardioSmart ST V 1.2/ V 1.3Page 25227 435 11 D

The function of the individual pins is given in the following table. The definition as an Input/Output is seen with reference to PCB Control_CS.

Pin Num- ber	Input/Out- put	Denotation	Function
1		NC	NC
2	Input	RXDE	Receive RS-232 data
3	Output	TXDE	Transmit RS-232 data
4		NC	NC
5	Output	GND	System ground
6,7,9		NC	NC
8	Input	REMOTE START	Remote Start Input

2.5.1.2 Patient input

Below is a list of the most important features of the patient input:

- Classification: cardiac floating
- Defibrillation-proof
- Simultaneous data acquisition from all leads
- Individual electrode monitoring
- Voltage feed for floating power supply via floating transformer
- Control and data signals from and to floating part via optoelectronic coupler

The connector is denoted: AA/

Male multipoint connector sub-D socket housing, 15-pin

Marquette Hellige GmbHCardioSmart/CardioSmart ST V 1.2/ V 1.3Page 27227 435 11 D

The function of the individual pins is given in the following table. The definition as an Input/Output is seen with reference to PCB Control_CS.

Pin Num- ber	Input/Out- put	Denotation	Function
1	Input	C2	Input electrode C2
2	Input	C3	Input electrode C3
3	Input	C4	Input electrode C4
			(Nap for Nehb cables)
4	Input	C5	Input electrode C5
5	Input	C6	Input electrode C6
6	Output	S	Shielding
7	Output	PLGND	Identification of patient cable used
8	Input	PL	Identification of patient cable used
9	Input	R	Input electrode R
10	Input	L	Input electrode L
11	Input	F	Input electrode F
12	Input	C1	Input electrode C1
13	Input	Nst	Input electrode Nst (for Nehb)
14	Output	Ν	Output electrode N (common mode compensation)
15	Input	Nax	Input electrode Nax (for Nehb)

2.6 Limitations

The following operating modes are not implemented in the CardioSmart:

- No ergometry
- No SAO2
- No spirometry
- No late potentials, no RR variability
- No phono, no US Doppler

A scope output is not available.

No analog inputs.

The existing RS-232 interface does not provide an ECG trigger output.

Recording without or with an empty NC battery is not possible.

Lead accumulators cannot be used.

Primary cells cannot be used.

3. System test functions

With country default setting German all messages displayed during the self-test are in German, in all other country settings they appear in English.

3.1 System test functions with graphics display

3.1.1. General information

The functions for the system test are mostly menu-guided.

For complete execution some tests require special auxiliary resources. These include interface testers or PC, connection cables, signal generators, etc. The tests that are necessary are described in the various test descriptions.

3.1.2 Test start

After simultaneously pressing the keys

Shift + Auto (CardioSmart) or **Shift + Mode** (CardioSmart ST)

the initial display menu appears to enable selection of a specific test. (see below) Keys used for menu selection appear in parenthesis.

System test

Test functions:

- (1) Display test
- (2) Key test
- (3) Motor test
- (4) Test results
- (5) Recording test
- (6) Interface test
- (7) Time and date
- (8) Electrode test
- (9) Time constant test
- (V) Device model (from SW V4.21)
- (C) 12SL / HEART (from V4.21)

Terminate with SH_MAN or SH_MODE key

3.1.3 Display test (1)

After pressing the "1" key the following menu appears:

Display test

- (1) Test pattern
- (2) Character set
- (3) Delete display
- (4) Inverse
- (5) Display illumination Contrast control
 - Shift Cursor Down
 - Shift_Cursor_Up
- Terminate with any key

Pressing any other key than one of those listed in the menu above leads back to the initial display menu.

(1) Test pattern

Pressing this key generates a chessboard pattern. Each subsequent pressing generates the inverse display of its predecessor.

(2) Character set

The character set used for the display is output.

(3) Delete display

All display pixels are inactive.

(4) Inverse

The contents of the existing display appear in reverse video.

(5) Display illumination

The illumination is switched on or off by pressing this key.

Contrast control

The contrast setting can always be adjusted as described above (cursor keys).

3.1.4 Key test (2)

By pressing the "2" key the following menu appears:

Key Test

- (P) Bleeper test
- (K) Cover for paper compartment
- (E) End

When a key is pressed this key or its function is displayed. This can either occur by a triple character display, e.g., "AAA" or as a text, e.g., "CURS_UP". Moreover, pressing the "P" key tests the bleeper (audible sound) and pressing the "K" key tests a micro key to identify whether the cover for the paper compartment is open or closed. The "E" key terminates this test and simultaneously undergoes a self-test.

3.1.5 Motor test (3)

When the "3" key is pressed the following menu appears:

Motor/Speed Test

- Speed select key
- Start/Stop
- (A) Measurement marking pulse ON
- (S) Measurement marking pulse OFF

The speed select key is used to set the required speed and the motor set into motion with Start/Stop.

Whilst running the motor speed can be controlled by using the "A" key to activate the setting of the measurement marking pulse and to deactivate it with the "S" key. A making pulse is set once every second. The running speed can then be calculated or its accuracy checked from the distance between marking pulses. Any other key pressed not included in this menu leads to the initial display menu.

3.1.6 Test results (4)

Pressing the "4" key triggers the output of the test results.

The output of the test protocol supplies data on the software integrated in the device (Part No., Version No., production date of the firmware), printhead voltage and the test results on the memory test performed during power-up. The areas listed under RAM have the following meaning:

CardioSmart

0 512 kByte	 080000h RAM area on the PCB Control CS_S
100000	- 140000h
256 kByte	RAM area on the CardioProm (depending on CardioProm type)
140000	- 1C0000h
512 kByte	RAM area buffered on the CardioProm (dep. on CardioProm type)

CardioSmart ST

0	- 080000h
512 kByte	RAM area on the PCB Control CS_S
100000 256 kByte	 180000h RAM area on the CardioProm (depending on CardioProm type)
180000	- 200000h
512 kByte	RAM area buffered on the CardioProm (dep. on CardioProm type)

Values may deviate from those given above, depending on the device or software version used.

A specification in the form 100000 - 100000 permits the conclusion that this RAM area does not exist in the device. However, if it does exist in conformity with the software version implemented, this means that this RAM cell at address 100000H is defective. The memory could also be defective when the initial and final addresses of the memory area differ and do not correspond to the above-mentioned limits. This then means, for example, that the specification 100000 - 123000 on the defective cell at address 123000H.

Following output the initial display menu reappears automatically.

3.1.7 Self-test

The test results elucidated in Section 3.1.6 are ascertained during the self-test, which is always performed on power-up. Should errors be detected, a message appears on the display after the test, indicating the possible errors. The following error codes are used to identify the error.

Error codes

The following error codes appear on the display together with the message "Self-test failed":

ERROR_CODES:	0	- reserved
	1	VEKT - error in vector table
	2	ERAM - RAM error on PCB Control
	3	LCDR - LCDRAM error (Graphics Display)
	4	- reserved
	5	- reserved
	6	RAMB - RAM error on the CardioProm
	7	GRAM - error in buffered RAM on the CardioProm
	8	ROMB - ROM error (checksum) on the CardioProm
	-	

9 - 10 not used

3.1.8 Recording test (5)

The recording test is activated by pressing the "5" key and interrupted with the "Start/Stop" key.

Immediately after pressing the "5" key the printer begins to record the first channels at 25mm/s and 20mm/mV.

In addition, the message "Recording test" appears on the display. In this test only the first two channels are passed on to the printer. No other channels can be configured.

3.1.9 Interface test (6)

Several possibilities are available to test the serial interface. Moreover, on the one hand, the signal transmission and receiving of the interface can be tested by an internal feedback from TXD and RXD and, on the other hand, the signal transmission and receiving with a remote station.

For the test with a remote station a standard PC cable is required for a serial interface (zero modem cable). In addition, the following transmission protocol should be adjusted at the remote station:

1 start bit, 8 data bits, parity even 1 stop bit Baud rate 9600

Pressing the "6" key calls up the following menu:

Interface test

(1) Transmitting and receiving

- (2) Transmit test string to device
- (3) Transmitting and receiving with device

(1) Transmitting and receiving

This test enables complete testing of the RS232 signal path for transmitting and receiving, including RS232 driver and connector.

This test requires an RS232 connector with an internal bridge from pin 2 (RXDE) to pin (TXDE). Depending on the result of the test, the following message appears:

Test result : OK or Test result : Error

This procedure requires a software version as from V4.1. Earlier software versions only permit internal testing of the RS232 interface without including the RS232 driver.

(2) Transmit test string to device

In this test a remote station, e.g., PC must be connected up and have a terminal program which can receive signals and be configured for the above-mentioned protocol. If the remote station is on receive, then every time the "2" key is pressed the test string "Interface test" is transmitted to the remote station. Simultaneously, the following message appears on the display:

Transmitting : interface test

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 35 227 435 11 D

(3) Transmitting and receiving with device

Transmitting and receiving can be tested with a remote device by pressing the "3" key. The device should be connected as described in (2).

After pressing the "3" key a test string is sent the remote station. The following message appears on the display:

Transmitting: interface test

Receiving:

A subsequent input at the remote station is sent back to the device and displayed there. Moreover, it should be noted that an input must take place within 10 s and the input terminated with "return". If the key is pressed a second time, then the string "CardioSmart Test" is transmitted. Altogether there are three test strings available, which are sent in the following sequence with repeated key activation: "Schnittstellenest", "CardioSmart Test", "Sieht doch gut aus, oder?" ("Interface Test", CardioSmart Test", Looks good, doesn't it?")

The last string corresponds to the expected test result. This test is terminated with any other key not used for a test.

3.1.10 Time and date (7)

This section deals with the quick checking and setting of the time and date. Pressing the "7" key calls up the following display:

> Time / Date 10:12:03 10.11.1994 (S) Set End with any key

From this screen the clock can be adjusted by pressing the "S" key, the following mask appearing:

Time	Date
[]	[]

The first mask is for the time and the second for the date. Example: [1012] [10119] for 10:12 o´clock and 10.11.94

Pressing the return key terminates the entry. The adjusted data are subsequently accepted and seconds set to zero.

The test is terminated with any other key not used for a test.

3.1.11 Electrode test (8)

The electrode test is started by pressing the "8" key.

The electrode test is terminated by pressing any key.

To evaluate the electrode states the following status WORD is available.

Status = 0 -> Electrode OK Status = 1 -> Electrode disconnected
Bit15 Bit0
x x DAT ELN NAP NST NAX C6 C5 C4 C3 C2 C1 F L R

And precisely this status WORD extended to LONG is displayed on the screen during the electrode test to be performed. It is important to note, however, that this status WORD is not displayed as a binary number but as a hexadecimal number.

However, to make the status of a particular electrode quickly recognizable, defective electrodes are represented by an ID code.

EX_R, for example, stands for the defective electrode R and C1 for electrode C1. This permits the identification of every individual electrode. Naturally, since several electrodes can become disconnected simultaneously, it was necessary to set a certain priority in the display of disconnected electrodes.

The following display priority was programmed:

EX_R, EL_N, EX_L, EX_F, C1, C2, C3, C4, C5, C6, NAX, NST, NAP

For example, if electrodes R and N have become disconnected, then first R is reported with EX_R as having become disconnected. Only after R is OK is EL_N displayed.

3.1.12 Test time constants (9)

The test is started by pressing the "9" key and interrupted with the "Start/Stop" key.

Immediately after the "9" key has been actuated the printer begins to record the first two channels at 25 mm/s and 20 mm/mV.

Moreover, the message "Testing time constants" appears on the display.

In this test only the first two channels send signals to the printer. No other channels can be configured. The default time constant is output on the printout as a control.

Setting the time constants

As a general rule, the time constants are adjusted to 2.04 s. This setting can be changed with the CORR_CONFIG key. The following settings are available:

Time constants:

(1) 0.260s (2) 0.130s (3) 0.033s (4) 0.004s (5) 4.080s (6) 2.040s (7) 1.020s (8) 0.510s

The figures given in parentheses indicate the key used to select the corresponding time constant.

Verification of the currently active time constant is only possible by printing out the self-test results (see Section 3.1.6) or by testing the time constants.

3.1.13 Setting the Device models (V)

The setting of the Device model is activated by pressing the "V" key, the following display image appears:

Device model

(1)	INT
(2)	USA
(3)	EU_2
(4)	ASIA
(5)	RUSS

Terminate with any key.

The currently selected device model appears in reverse video.

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 38 227 435 11 D

Warning!

Changing the device model affects the selection of the output formats and languages available, can switch the program for Interpretation from HEART to 12 SL, or vice versa. Also affected are the default configuration settings, e.g., override function yes/no, line filter 50/60 Hz.

The device model configured during manufacture should only be changed when deemed really necessary.

Device model Interpretation		Output	Languages	Default settings		
			formats		Override function enabled	Line filter
01	INT	HEART	International	g,e,f,i,s	no	50 Hz
02	USA	12SL	USA	e,f,s	yes	60 Hz
03	EU_2	12SL	Int. +H1 +H2	e,g,f,sw	yes	50 Hz
04	ASIA	HEART	International	g,e,f	no	50 Hz
05	RUSS	HEART	International	g,e,f	no	50 Hz

The following table shows the most important combinations:

Output formats: - International: 12_FS, 12_F1, 12_F2, 6_F1, 6_F2, 3_F1

- USA: STND1, STND3, 1x10, 2x5, 2x5_ex, 3RHY1

The required device model is selected by pressing the appropriate key, "1" to "5". Quit selection menu by pressing any key.

Quit the self-test with "Shift" + "Man" or "Shift" + "Mode".

CardioSmart configures the appropriate items and initiates a cold start automatically. Thus, when the device is rebooted automatically all the new settings are adopted.

Selecting a particular device model leads to the configuration of the program for Interpretation as indicated in the table above, even when the interpretation program was configured differently beforehand as described in section 3.1.14.

Note on saved ECGs when configuring the device model:

Saved ECGs are not lost.

If when a new device model is selected, the program for Interpretation is switched over, however, when printing out the saved ECGs the display in the status line (12SL, or without in the case of HEART) is related to the currently enabled program for

Interpretation, although the results are based on the program previously configured. In this case, the saved ECGs should be printed out or transferred to a PC before configuration of the new model.

3.1.14 Switching over the program for Interpretation(C)

Switching over the program for Interpretation is activated by pressing the "C" key, the following display image appears:

Interpretation

- (1) HEART
- (2) 12SL

Terminate with any key.

The currently enabled interpretation program appears in reverse video.

Warning!

Switching over to another program for Interpretation affects the measurement results and the interpretation!

The program for Interpretation configured during manufacture should only be changed when deemed really necessary!

The required program for Interpretation is selected by pressing the appropriate key, "1" or "2".

Quit the selection menu by pressing any key.

Quit the self-test with "Shift" + "Man" or "Shift" + "Mode".

CardioSmart configures the appropriate items and initiates a cold start automatically.

Thus, when the device is rebooted automatically all the new settings are adopted.

Note on saved ECGs when switching over the progran for Interpretation:

Saved ECGs are not lost.

After switching over to a different program for Interpretation when printing the saved ECGs the display in the status line (12SL, or without in the case of HEART) is related to the newly selected interpretation program, although the results are based on the program previously configured. In this case the saved ECGs should be printed out or transferred to a PC before switching over to the new program for Interpretation.

3.2 Device test functions with character display (only CardioSmart)

3.2.1 General information

In contrast to the graphics display, at the current time the device test functions all require menu-guided execution. This is because the rendition of the character display of max. 80 characters is very limited.

To be performed in their entirety some tests require special auxiliary aids, e.g., interface tester or PC, connection cables, signal generators, etc. Just what is required for which test are given in the various test descriptions.

3.2.2 Test start

After simultaneous pressing of the keys

```
Shift + Auto (CardioSmart) or Shift + Mode (CardioSmart ST)
```

the following initial display image appears:

```
SYSTEM TEST
END TEST: with Shift MAN (CardioSmart) or Shift + Mode
(CardioSmart ST)
```

Key used to select menu options are given in parentheses.

3.2.3 Display test (1)

After pressing the "1" key the following menu appears:

Display test (3) Delete display (4) Inverse

Pressing any other key than those given above leads back to the initial display image.

(3) Delete display

All the display pixels are disabled.

(4) Inverse

Inverse here does not mean inverse display of the rendered text, but inverse to delete display, i.e., all the display pixels are enabled.

Contrast control

Furthermore, the contrast control can also be adjusted under this option "Display test". Moreover, there are 7 levels available which can be run though with the CURSOR_UP and CURSOR_DOWN keys.

3.2.4 Key test (2)

Pressing the "2" key calls up the following screen:

Key Test (E) End

When a key is pressed this or its meaning is displayed. This can either occur by a triple character display, e.g., "AAA" or as a text, e.g., "CURS_UP". Moreover, pressing the "P" key tests the bleeper (audible sound) and pressing the "K" key tests a micro key to identify whether the cover for the paper compartment is open or closed. The "E" key terminates this test and simultaneously undergoes a self-test. The initial display image appears.

3.2.5 Motor test (3)

When the "3" key is pressed the following menu appears:

Motor/Speed Test

The speed select key is used to set the required speed and the motor set into motion with Start/Stop.

Whilst running the motor speed can be controlled by using the "A" key to activate the setting of the measurement marking pulse and to deactivate it with the "S" key. A marking pulse is set once every second. The running speed can then be calculated or its accuracy checked from the distance between marking pulses.

Any other key pressed not included in this menu leads to the initial display menu.

3.2.6 Test results (4)

Pressing the "4" key triggers the output of the test results.

The output of the test protocol supplies data on the software integrated in the device (Part No., Version No., production date of the firmware), printhead voltage and the test results on the memory test performed during power-up.

The areas listed under RAM have the following meaning:

CardioSmart

	0 512 kByte	 080000h RAM area on the PCB Control CS_S
	100000 256 kByte	 140000h RAM area on the CardioProm (depending on CardioProm type)
type)	140000 512 kByte	- 1C0000h RAM area buffered on the CardioProm (dep. on CardioProm

CardioSmart ST

0 512 kByte	 080000h RAM area on the PCB Control CS_S
100000	 180000h
256 kByte	RAM area on the CardioProm (depending on CardioProm type)
180000	 200000h
512 kByte	RAM area buffered on the CardioProm (dep. on CardioProm

type)

Values may deviate from those given above depending on the device or software version used.

A specification in the form 100000 - 100000 permits the conclusion that this RAM area does not exist in the device. However, if it does exist in conformity with the software version implemented, this means that this RAM cell at address 100000H is defective. The memory could also be defective when the initial and final addresses of the memory area differ and do not correspond to the above-mentioned limits. This then means, for example, that the specification 100000 - 123000 on the defective cell at address 123000H.

The output can be interrupted with the Start/Stop key. Following output the initial

display menu reappears automatically.

3.2.7 Self-test

The test results elucidated in Section 3.2.6 are ascertained during the self-test, which is always performed on power-up. Should errors be detected, a message appears on the display after the test indicating the possible errors. The following error codes are used to identify the error.

Error codes

The following error codes appear on the display together with the message "Self-test failed":

ERROR_CODES: 0 - reserved 1 VEKT - error in vector table - RAM error on PCB Control 2 ERAM 3 LCDR - LCDRAM error (Graphics Display) 4 - reserved 5 - reserved 6 RAMB - RAM error on the CardioProm 7 GRAM - error in buffered RAM on the CardioProm - ROM error (checksum) on the CardioProm 8 ROMB 9 - 10 not used

3.2.8 Recording test (5)

The recording test is activated by pressing the "5" key and interrupted with the "Start/Stop" key.

Immediately after pressing the "5" key the printer begins to record the first channels at 25mm/s and 20mm/mV.

In addition, the message "Recording test" appears on the display. In this test only the first two channels are passed on to the printer. No other channels can be configured.

3.2.9 Interface test (6)

Several possibilities are available to test the serial interface. Moreover, on the one hand, the signal transmission and receiving of the interface can be tested by an internal feedback from TXD and RXD and, on the other hand, the signal transmission and receiving with a remote station.

For the test with a remote station a standard PC cable is required for a serial interface (zero modem cable). In addition, the following transmission protocol should be adjusted at the remote station:

1 start bit, 8 data bits, parity even 1 stop bit Baud rate 9600

Pressing the "6" key calls up the following menu:

Interface test Keys (1), (2), (3) '1' key tests transmission and receiving

(1) Transmitting and receiving

This test enables complete testing of the RS232 signal path for transmitting and receiving, including RS232 driver and connector.

This test requires an RS232 connector with an internal bridge from pin 2 (RXDE) to pin (TXDE). Depending on the result of the test, the following message appears:

Test result : OK or Test result : Error

This procedure requires a software version as from V4.1. Earlier software versions only permit internal testing of the RS232 interface without including the RS232 driver.

(2) Transmit test string to device

In this test a remote station, e.g., PC must be connected up and have a terminal program which can receive signals and be configured for the above-mentioned protocol. If the remote station is on receive, then every time the "2" key is actuated the test string "Interface test" is transmitted to the remote station. Simultaneously, the following message appears on the display:

Transmitting : interface test

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 45 227 435 11 D

(3) Transmitting and receiving with device

Transmitting and receiving can be tested with a remote device by pressing the "3" key. The device should be connected as described in (2).

After pressing the "3" key a test string is sent the remote station. The following message appears on the display:

Interface test Keys (1), (2), (3)

A subsequent input at the remote station is sent back to the device and displayed there. A received text would then be displayed on the second line of the screen.

Moreover, it should be noted that an input must take place within 10 s and the input terminated with "return". If the key is actuated a second time then the string "CardioSmart Test" is transmitted. Altogether there are three test strings available, which are sent in the following sequence with repeated key actuation:

"Interface Test", "CardioSmart Test", "Looks good, doesn't it?"

The last string corresponds to the expected test result. This test is terminated with any other key not used to start a test.

3.2.10 Time and date (7)

This section deals with the quick checking and setting of the time and date. Pressing the "7" key calls up the following display:

Time /	Date
10:12:03	10.11.1994

From this screen the clock can be adjusted by pressing the "S" key the following mask appearing:

TimeDate[][]

The first mask is for the time and the second for the date. Example: [1012] [10119] for 10:12 o´clock and 10.11.94

Pressing the return key terminates the entry. The adjusted data are subsequently accepted and seconds set to zero.

The test is terminated with any other key not used for a test.

3.2.11 Electrode test (8)

The electrode test is started by pressing the "8" key.

The electrode test is terminated by pressing any key.

To evaluate the electrode states the following status WORD is available.

And precisely this status WORD extended to LONG is displayed on the screen during the electrode test to be performed. It is important to note, however, that this status WORD is not displayed as a binary number but as a hexadecimal number.

However, to make the status of a particular electrode quickly recognizable, defective electrodes are represented by an ID code. EX_R, for example, stands for the defective electrode R and C1 for electrode C1.

This permits the identification of every individual electrode. Naturally, since several electrodes can become disconnected simultaneously, it was necessary to set a certain priority in the display of disconnected electrodes.

The following display priority was programmed:

EX_R, EL_N, EX_L, EX_F, C1, C2, C3, C4, C5, C6, NAX, NST, NAP

For example, if electrodes R and N have become disconnected, then first R is reported with EX_R as having become disconnected. Only after R is OK is EL_N displayed.

3.2.12 Test time constants (9)

The test is started by pressing the "9" key and interrupted with the "Start/Stop" key.

Immediately after the "9" key has been actuated the printer begins to record the first two channels at 25 mm/s and 20 mm/mV.

Moreover, the message "Testing time constants" appears on the display.

In this test only the first two channels send signals to the printer. No other channels can be configured. The default time constant is output on the printout as a control.

Setting the time constants

As a general rule, the time constants are adjusted to 2.04 s. This setting can be changed with the CORR_CONFIG key. The following settings are available:

Time constants:

(1) 0.260s	(2) 0.130s	(3) 0.033s
(4) 0.004s	(5) 4.080s	(6) 2.040s
(7) 1.020s	(8) 0.510s	

The figures given in parentheses indicate the key used to select the corresponding time constant.

Verification of the currently active time constant is only possible by printing out the self-test results (see Section 3.2.6) or by testing the time constants (see Section 5.2.8).

3.2.13 Setting the Device model (V)

This setting is only available form Software Release V4.21.

Setting the Device model is activated by pressing the "V" key, the following display image appears:

Device Model --> (1) INT

(1) INT (2) USA (3) EU_2 (4) ASIA (5) RUSS

Terminate with any key. The currently enabled device model appears in line 1.

Warning!

Changing the device model affects the selection of the output formats and languages available, can switch the program for Interpretation from HEART to 12 SL, or vice versa. Also affected are the default configuration settings, e.g., override function yes/no, line filter 50/60 Hz.

The device model configured during manufacture should only be changed when deemed really necessary.

The following table shows the most important combinations:

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 48 227 435 11 D

Device model	Interpretation	Output	Languages	Default settings		
			formats	formats	Override function enabled	Line filter
01	INT	HEART	International	g,e,f,i,s	no	50 Hz
02	USA	12SL	USA	e,f,s	yes	60 Hz
03	EU_2	12SL	Int. +H1 +H2	e,g,f,sw	yes	50 Hz
04	ASIA	HEART	International	g,e,f	no	50 Hz
05	RUSS	HEART	International	g,e,f	no	50 Hz

Output formats: - International: 12_FS, 12_F1, 12_F2, 6_1F, 6_F2, 3_F1

- USA: STND1, STND3, 1x10, 2x5, 2x5_ex, 3RHY1

The required device model is selected by pressing the appropriate key, "1" to "5". Quit selection menu by pressing any key.

Quit the self-test with "Shift" + "Man" or "Shift" + "Mode".

CardioSmart configures the appropriate items and initiates a cold start automatically. Thus, when the device is rebooted automatically all the new settings are adopted.

Selecting a particular device model leads to the configuration of the program for Interpretation as indicated in the table above, even when the interpretation program was configured differently beforehand as described in section 3.2.14.

Note on saved ECGs when configuring the device model:

Saved ECGs are not lost.

If when a new device model is selected, the program for Interpretation is switched over, however, when printing out the saved ECGs the display in the status line (12SL, or without in the case of HEART) is related to the currently enabled program for Interpretation, although the results are based on the program previously configured. In this case, the saved ECGs should be printed out or transferred to a PC before configuration of the new model.

3.2.14 Switching over the program for Interpretation (C)

Switching over the program for interpretation is activated by pressing the "C" key, the following display image appears:

Interpretation --> (1) HEART

Terminate with any key.

The currently enabled device model appears in line 1.

Warning!

Switching over to another program for Interpretation affects the measurement results and the interpretation!

The program for Interpretation configured during manufacture should only be changed when deemed really necessary!

The required program for Interpretation is selected by pressing the appropriate key, "1" or "2":

"1" for HEART, or "2" for 12SL.

Quit the selection menu by pressing any key.

Quit the self-test with "Shift" + "Man" or "Shift" + "Mode".

CardioSmart configures the appropriate items and initiates a cold start automatically. Thus, when the device is rebooted automatically all the new settings are adopted.

Note on saved ECGs when switching over the progran for Interpretation:

Saved ECGs are not lost.

After switching over to a different program for Interpretation when printing the saved ECGs the display in the status line (12SL, or without in the case of HEART) is related to the newly selected interpretation program, although the results are based on the program previously configured. In this case the saved ECGs should be printed out or transferred to a PC before switching over to the new program for Interpretation.

4. Repair instructions

4.1. Safety instructions

Repairs may only be conducted by approved specialist personnel. Before opening the CardioSmart switch off device and disconnect mains plug! Never connect mains plug when the when the device is open!

Before replacing the primary fuses in the power input module or when resetting the voltage selector switch to a different voltage range the device should also be switched off and the mains plug disconnected!

When replacing electronic components implement **ESD protection.** Return replaced PCBs in **ESD packaging** only.

Defective batteries, empty batteries should be **disposed of in accordance with the applicable legal stipulations** or returned to the factory. Batteries returned to the factory should be labeled **'For disposal**'.

4.2 Replacing components

For all the following points the safety instructions in Section 4.1. are to be observed!

The CardioProm (program module) can be unlocked with a coin and then pulled out. The character display CardioVision Text can be disengaged without opening the device by applying a screwdriver three times left, right and in the middle between the display housing and the upper housing shell of the CardioSmart. **Warning:** The device must be switched off!

Opening the device

To open the CardioSmart undo the 5 fastening screws on the underside of the device, open the paper feed flap, carefully raise the upper shell of the housing, disconnect keypad. The display remains in the upper shell of the casing.

During reassembly ensure that no cables are pinched. Exert gentle pressure in the vicinity of the display to ensure that the display is in contact with the PCB and that it remains snapped into position in the upper shell.

Replacing the mains input module

After opening the device undo the screw located on the underside of the housing used to secure the holding angle bracket for the mains input module and the device poweron switch. Disconnect the primary connector DC and switch on/off connector DA from the PCB Power Supply.

Replace mains input module (snap-in connection).

Warning: Only use fuses indicated on the rating plate! (see Chapter 8, Parts List)

For safety reasons insert the fuse holder such that the correct mains voltage range is adjusted!

Visual check at the inspection window of the mains input module. (see Section 2.4)

Replacing the battery

Disconnect and lift out the battery compartment on the underside of the device by raising the middle fastening catch. Remove the battery and disconnect the battery plug DD from the PCB Power Supply.

Warning: Only original Marquette Hellige batteries may be used! (see Chapter 8, Parts List)

Defective batteries, empty batteries should be **disposed of in accordance with the applicable legal stipulations** or returned to the factory. Batteries returned to the factory should be labeled **"For disposal"**.

Before putting in the new battery insert plug DD. Push in battery compartment, secure by pressing on the fastening catch.

Replacing the PCB Power Supply

After opening the device first of all disconnect the primary connector DC and the switch on/off connector DA from the PCB Power Supply. Open the battery compartment and disconnect the battery connector DD (see "Replacing the battery").

Disconnect connector AE from the PCB Control. Remove PCB Control (see "Replacing the PCB Control").

Undo the 2 fastening screws next to the transformer and fuse Si500.

PCB Control has 2 soldered fuses:

- SI 500: Battery fuse
- SI 501: Secondary circuit fuse

No adjustments on the PCB Control are necessary.

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 53 227 435 11 D

Replacing the PCB Control

With the transition to device version V1.2 the PCB Control has a new part number:

PCB Control CS_S equipped: 388 032 13, Spare Part No: 389 004 16

Before replacing the PCB, if still possible, printout the settings configured by the user.

After opening the device first of all disconnect the plug-in connector AE to the power supply unit, then disconnect the remaining connectors to the recording unit. Undo the 6 PCBs fastening screws.

Remove shielding plate under the patient input section (1 screw, 3 x snap-in catches) and assemble it on the new PCB.

Check whether the lithium battery for the real-time clock (BA 500) is correctly soldered. Insert new PCB and plug in connectors.

Since the motor controller is located on the PCB Control, the motor adjustment for speed and compensation must be carried out. Motor adjustment is described in Chapter 6.

In addition, disengage the retaining clips by pressing them together, then remove from the upper shell and plug into the connector AG (character display) or AH (graphics display). However, simpler is a character LCD module connected to connector AG via a flat strip cable.

Connect keypad in the upper shell using connector AS.

Setting the time (Section 3.1.10 / 3.2.10).

If known, adopt the user-programmed configuration; otherwise, default setting.

If known, reset the user-programmed time constants; otherwise by outputting the self-test results (Section 3.1.6 / 3.2.6).

Check default setting is 2.04 s, and adjust to 2.04 s if necessary (Section 3.1.12 / 3.2.12)

Adjust contrast with the appropriate display.

Replacing the motor

After replacing the motor the motor adjustment of speed and compensation must be carried out as described in Chapter 6.

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 54 227 435 11 D

Replacing the graphics display

The CardioSmart must be opened to be able to replace the graphics display. Disengage the graphics display from the upper shell of the housing by pressing together the retaining clips and remove it.

Reassemble the upper shell. Then carefully insert the graphics display into the basic device until the retaining clips snap securely into place.

Adjust the contrast with the new display.

Replacing the character display

The character display CardioVision Text can be disengaged without opening the device by applying a screwdriver three times to the left, right and in the middle between the display housing and the upper shell of the CardioSmart housing. Carefully insert the new display (character or graphics) into the basic device until the retaining clips snap securely into place.

Adjust the contrast with the new display.

Replacing pump module

Open device, take care in removing the upper shell to avoid damage to vacuum tubing. Detach the vacuum tubing from the upper shell. Disconnect power plug SA from the pump module. The module can be replaced after unscrewing the two fastening screws and detaching the evacuated air tubes.

After replacement perform a performance check as described in section 7.1.2.11.

Take the negative pressure reading at PTT after approx. 10 s. This value must lie within the range 225...265 mmHg (300...350 mbar).

5. Troubleshooting tips

Device cannot be switched on even though power plug is plugged in

- green power lamp LED is off and device cannot be switched on:

- power cable defective or not plugged in correctly?
- primary fuses in the mains input module defective?
- connecter DC on PCB Power Supply plugged in correctly?
- mains input module defective?
- keypad via connector AS on PCB Control plugged in correctly?
- are all above-mentioned points OK: ===> PCB Power Supply defective (transformer or rectifier)

- green power lamp LED is on, but device still cannot be switched on:

- device on/off switch or its lead defective?
- connector DA on PCB Power Supply plugged in correctly?
- keep device on switch depressed and measure voltage UVERS on connector AE pins 4 + 5 on PCB Control: UVERS greater that 25V-?
 - if not: fuse SI501 on PCB Power Supply defective?
 - if SI501 OK ===> PCB Power Supply defective.
 - if so: ===> PCB Power Supply defective.

Device cannot be switched on when being battery-operated only

- Is the battery empty?

- Plug in power plug, green power lamp LED should glow and the device can be activated, if not, refer to "Device cannot be switched on even though power plug is plugged in".

- By connecting the power plug rapid charging is activated, LED1 on PCB Power Supply should glow, via the PTC resistor R500 a power supply of approx 1 V should be available on PCB Power Supply.

(measured with a multimeter):

- if so: battery charging circuit OK.
- if not: battery disconnected or defective?
- if not: ===> error on PCB Power Supply

- After charging for 10 minutes disconnect power plug, can the device be switched on and trigger a recording?

- if not: - fuse SI500 on PCB Power Supply defective? (Device does not switch on)

- if SI500 OK ===> battery defective or capacity too small.

No display on the screen

- does the yellow Stop LED on the keypad glow after the device is switched on?

- if not: - refer to "Device cannot be switched on"

(if the green Start LED glows CardioProm can also be defective) - contrast badly adjusted (adjust contrast)

- graphics display: can the background illumination be activated by pressing a key?

- does a beep sound approx. 10s after switching on the CardioSmart? (indicates that the self-test is over)

- if so: display correctly engaged?
- if so: ===> display defective?

===> or driver on the PCB Control defective

- if not: - error in basic device:

===> PCB Control defective?

===> or CardioProm defective

Error in self-test identified

When an error is detected during the self-test, in addition to the message "Self-test failed" the error code number and a short description also appear on the display. The meaning of the error codes is described in Section 3.1.7 / 3.2.7. The error codes refer to the PCB Control, graphics display and the CardioProm:

- error code 1, 2: PCB Control
- error code 3: PCB Graphics Display
- error code 6,7,8: CardioProm

CardioSmart fails to give printout, no paper transport

Perform the following test in the manual operating mode:

- Paper available? Paper correctly inserted? Paper transport defective?

- Paper feed flap correctly engaged on both sides?
- after pressing the Start key the green Start LED must glow
 - if not: ===> CardioProm defective?

===> or PCB Control defective

- Power supply +/-12V at test connector AF/pin 1 and pin 3 of PCB Control available?

- if not: Signal REG_ON on high-level? (Measure at connector AE/pin 2)
- if not: ===> CardioProm defective?
 - ===> or PCB Control defective
 - Signal REG_OFF on high-level (Measure at connector AE/pin 11)
- if not: ===> Battery depleted or defective?
 - ===> or PCB Power Supply defective
- Motor feed line defective? Connector AK plugged in correctly?
- Motor blocked? (check roller, transmission)

- Measuring voltage COMMON_S at test connector AF/pin 4 of the PCB Control available in the range 16V ... 23V?
 - if so: ===> Motor defective?

===> or PCB Control defective (Motor controller)

- if not: - Battery voltage too low, recharge

Paper transport functions, no printout

- Paper feed flap correctly engaged on both sides?

- Printhead impact pressure switch OK? In addition, in the system test Sections
- 3.1.4/3.2.4 use the "K" key to check whether opening/closing of the switch is identified.
- if not: Is connector AJ on PCB Control inserted correctly?
- Good feed line contact on printhead impact pressure switch?
- Printhead impact pressure switch defective?

- Printhead power supply on? Measurement at plus terminal of C500 on PCB Control, voltage in range 16V ... 23V

- if not: Signal REG_ON on high-level? (Measure at connector AE/pin 2)
- if not: ===> CardioProm defective?

===> or PCB Control defective

- Signal REG_OFF on high-level? (Measure at connector AE/pin 11)
- if not: ===> Battery depleted or defective?

===> or PCB Power Supply defective

- if both signals are on high:
- ===> PCB Control defective (common/VDD1 switch)
- Printhead power supply cable (connector AO) defective, or not plugged in correctly?
- Printhead data feed line (connector AL) defective, or not plugged in correctly?
- After an extensive printjob, printhead still overheated? Allow to cool.
- none of the above-mentioned errors apply:

===> PCB Control defective?

===> or thermal array printhead defective

CardioSmart only prints on the upper or lower section of the printout

- Paper feed flap is only engaged on one side.

CardioSmart prints, but only baselines are printed out

- Electrodes applied correctly?
- Electrode cables plugged into the patient trunk cable terminal box correctly?
- Patient trunk cable defective (e.g., N core defective)
- Contact problems at the patient input of the CardioSmart?
- none of the above-mentioned errors apply: ===> PCB Control defective

6. Adjustment instructions

CardioSmart only requires motor adjustment. Adjustment is necessary when a new motor (replacement of paper feed flap) or a new PCB Control is implemented.

Motor Adjustment

What to adjust or to check?	What to measure with?	How to adjust test mode?	Where to turn?	How much and exact?	What else to note?
Motor speed under small load, slow down driving roller by applying a finger (recorder flap open), adjust on stationary motor pinion.	Flash at motor pinion with a stroboscope (LED)	 Shift + Auto "3" key "A" key With mm/s key adjust to 25mm/s 5. START key 	Speed adjuster R505	Stroboscope frequency = 283.6 Hz When an LED driven by a square-wave generator is used- , a small key ratio should be observed.	Motor should be at room temperature be switched on for only 5 s for each adjustment.
Adjust motor speed on the slowed down driving roller, so that there is no difference in the RPM. Slow down the driving roller with a finger sufficiently, so that the LED500 just remains illuminated. (Recorder flap open)	see above	see above	Speed compensation R506	see above	If the RPM has changed after compensation adjustment, it should be corrected again with R505.

When a stroboscope is not available:

What to adjust or to check?	What to measure with?	How to adjust test mode?	Where to turn?	How much and exact?	What else to note?
Adjust motor speed with the recorder flap closed.	Check the measurements of the grid with a ruler. min. 200mm	 Shift + Auto "3" key "A" key With mm/s key adjust to 25mm/s 5. START key 	Speed adjuster R505	< 0,5%	Motor should be at room temperature be switched on for only 5 s for each adjustment.
With an increased load adjust motor speed (additional speed reduction, finger on the driving roller until LED 500 just goes out)	see above	see above	Speed compensation R506	see above	The adjustment procedure is complete when the RPM is 25 mm/s both under normal and increased load.

Page 60

7. Servicing and maintenance

7.1 Technical inspection

A technical inspection is to be performed once a year. The following items, including the accessories used, are to be performed:

- Check device and accessories for mechanical defects which impair their function.

- Perform a function check as detailed in Section 3 "System test functions".

- Check labels and inscriptions on the device relating to safety are clearly legible.

- Measure the resistance of the non-fused earth conductor as per measuring circuit from VDE 0751:1990

- Measure the device leakage current as per measuring circuit from VDE 0751:1990

- Measure the patient leakage current as per measuring circuit fromVDE 0751:1990

Warning!

The following checks may only be performed by persons whose training, knowledge and practical experience enable them to carry out such checks reliably and correctly.

Notes:

The operational and functional reliability of the device is checked using the following checklists.

They serve the experienced technician when checking the device.

A knowledge of device operation as detailed in the "User's Manual" is assumed.

The checklist items are based on the testing instruments given below.

The tests should be carried out using the customer's accessories, so that defective accessories are also detected automatically.

If other testing instruments are used besides those mentioned, the items on the check list and tolerance specifications may need to be modified.

7.1.1 Visual check

Device and accessories are to be checked to ensure that

- fuse cartridges comply with vendor's specifications;
- labels and inscriptions on the device relating to safety are clearly legible;
- the mechanical state of the device permits its further use;
- there is no fouling which could cause any reduction in safety.

7.1.2 Test functions

7.1.2.1 Recommended testing instruments and accessories

1x	Multi-parameter simulator Lionheart
1x	RS232 interface connector with internal connection between pins 2 and 3 (TXD and RXD)
1x	Patient trunk cable and customer electrode leads, or 1X patient trunk cable, 10-pin 233 402 04 with 1 set of electrode leads (10 leads) with 4 mm plugs 38401129
1x mmHg)	Pneumatic Transdurcer Tester PTT, for example: X - Caliber (Display in

1x 1 x Y-Adapter 303 444 89

7.1.2.2 Test preparations

The following descriptions apply to device version V1.2 and software version V4.2.

In general, the device test functions implemented in CardioSmart are used for the tests. These are described in Section "3. Device test functions".

Connect CardioSmart up to the mains, the green LED for standby must glow. Switch the device on, the self-test runs automatically, no error message should appear. When the self-test has finished the device is in the automatic mode, the yellow LED for still disabled operating mode must glow.

Modifications in the user-programmed configuration may need to be made in order to carry out the test. Should such a change need to be made to enable testing, make a printout of all the modified configuration lists and mark the changes made.

Important: After completing the test the original user-programmed configuration is to be retrieved and activated.

7.1.2.3 Operating and display unit performance tests

- Carry out the "Display test (1)" as detailed in Sections 3.1.3 and 3.2.3, respectively.

- Carry out the "Keypad test (2)" as detailed in Sections 3.1.4 and 3.2.4, respectively.

7.1.2.4 Test for recording speeds 25 and 50 mm/s

- Carry out the "Motor test (3)" as detailed in Sections 3.1.5 and 3.2.5, respectively.
- Enable measurement marks by pressing the "A" key.
- Should there be feed speed deviations of > 2%, adjust motor as detailed in Section "6 Adjustment instructions".

7.1.2.5 Device test result check

- Output "Test results 4)" as detailed in Sections 3.1.6 and 3.2.6, respectively.
 - Main parameters: all memory stores free from error?
 - ASIC test O.K?
 - Sample rate 1000?
 - Selected time constants: 2.04 s (or 4.08 s)?
 - Printhead voltage > 18V, battery charge O.K?
 - Printout clearly legible and without any lapses or

interference?

7.1.2.6 RS232 interface test

- Carry out the "Interface test (6)" test item "(1) Transmitting and receiving".
 - Note: For devices with CardioProms V3.0x the RS232 driver is not yet tested in this test; therefore, in this case test item "(3) Transmitting and receiving with device" should be carried out.
- Remote start input test:
 - Adapt push button (NO contact) between RS232 interface pin 8 and pin 5
 - Select manual mode
 - Press push button once: initiates recording in manual mode
 - Press again: terminates recording in manual mode

7.1.2.7 Analysis of the ECG signals and HR value

Carry out the following settings on the ECG simulator:

1 mV

- Amplitude
- Heart rate (RATE) 60 bpm

Connect the electrode leads as indicated below:

R	red	>	RA
L	yellow	>	LA
F	green	>	LL
Ν	black	>	RL
C1	white/red	>	V1
:	:	:	
C6	white/violet	>	V6

Switch in manual operating mode and start recording by pressing the Start key.

By pressing the lead scrolling key check whether all leads **are being recorded**. The ECG traces must be **noise-free**.

Record one page in the "manual" operating mode. The following annotations must be present:

- Heart rate (top right)
- Lower status line date and time
 - recording speed
 - sensitivity
 - active filter, e.g., 50/60 Hz, 35/20 Hz, ADS
 - frequency range of the recording (not at SW level V3.0x)

The **heart rate** of 60 bpm +/- 2 bpm appears on the display and is printed out on the recording.

Activate the square-wave function on the ECG transmitter at 1 mV. Using the lead scrolling key select lead II. The square-wave pulse trace must correspond in **amplitude** with the displayed 1 mV reference pulse (applicable to named transmitter only).

Switch back to ECG signal on the ECG transmitter. Start the recording in manual mode.

Increase the heart rate to 200 bpm on the ECG transmitter. The acoustic warning signal must sound for about 1s. Reduce the heart rate back to 60 bpm, the warning signal no longer sounds.

7.1.2.8 Pacemaker identification test

Make the following settings on the multifunction simulator:

- pace setting
- pace amplitude 6 mV
- pace duration 0.2 ms

Adjust manual mode on CardioSmart device to be tested and select lead groups I, II and III.

Start the recording. The pace pulses must be visible as needles on the recording output.

7.1.2.9 Identification of disconnected electrodes

Reset the simulator to ECG signal at a heart rate of 60 bpm. Remove one electrode after the other from the ECG transmitter.

Activate the automatic mode in the CardioSmart device to be tested without activating it by pressing the Start key.

Check to ensure that each disconnected electrode is displayed correctly and that an acoustic alarm signal sounds.

7.1.2.10 Checking the charge status of the NC battery

The NC battery can, among other things, be checked as follows: discharging the battery, followed by charging up completelyl (duration 4 h), followed by discharging in standby mode without recording.

If the operating time for this procedure is under 2.5 h, the battery should be replaced.

7.1.2.11 Pump leakage

Start the pump by< blowing against the suction pipe still open and then closing the pipe with your finger as shown in the test setup (within 3 s). Take the negative pressure reading at PTT after approx. 10 s. This value must lie within the range 225...265 mmHg (300...350 mbar). Then switch off the negative pressure pump (ECG recorder or power supply unit). The drop in negative pressure must not exceed max. 1 mmHg/s (1.33 mbar/s).

If this value is not observed, the pump in the CardioSmart must be replaced .

Marquette Hellige GmbH CardioSmart/CardioSmart ST V 1.2/ V 1.3 Page 66 227 435 11 D

7.1.3. Safety Analysis Test

7.1.3.1 General Information

The suggested Safety Analysis Test refer to the international Standard IEC 601-1. The tests are generally performed with Safety Testers, on most of them, the measuring circuits according IEC 601 are already implemented.

The tests which have to be performed are described generally, for the handling of your Safety Tester follow the user manual.

The tests may be performed under normal ambient conditions of temperature, humidity and pressure and with line voltage.

The leakage currents correspond to 110 % of rated voltage for the tested unit. Most Safety Testers take this into account, otherwise the measured values have to be calculated.

Recommendet test equipment

- Safety Tester for measurements according IEC 601.
- Testing connector according the following description.

Testing connector for measuring patient leakage current.

For testing the ECG input, a patient cable, with all leads connected together, is used.

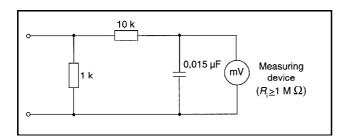
7.1.3.2 Protective earth resistance test

The protective earth resistance test has to be performed including its power cord. This test determins whether the device has a power ground fault.

- The protective earth resistance from power connector to any protective earth connected exposed conductive part is measured.
- Specs. of test circuit: AC current source 50 Hz/60 Hz of at least 10 A up to 25 A with limited output voltage of 6 V.
- If resistance is greater than 100 mOhm

7.1.3.3 Measuring of leakage current

To proceed the suggested measurements, the unit under test has to be separated from any interconnection to a system. If the unit is part of a system, extended tests according IEC 601-1-1 have to be performed. The following diagram shows the needed Measuring Circuit [M] for leakage current. The reading in mV corresponds to uA (leakage current). The Safety Testers generally work with this Measuring Circuit [M] and the displayed values are already converted to leakage current.



7.1.3.3.1 Enclosure Leakage Current Test

This test is performed to measure leakage current from chassis to ground during normal conditions (N.C.) and single fault conditions (S.F.C.). In any case, the leakage current is measured from any exposed conductive parts to ground, the unit under test has to be switched on and off.

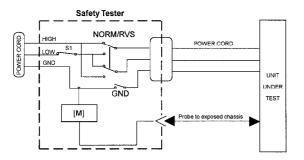
Connect the unit under test to your Safety Tester.

- During normal conditions (N.C.), referring to the electrical diagram, measurements have to be done under following conditions:
- * Polarity switch Norm and RVS
- * GND switch GND closed
- * S1 closed and open
- During single fault conditions (S.F.C.), referring to the electrical diagram, the measurements have to be done under following conditions:
- * Polarity switch NORM and RVS
- * GND switch GND open
- * S1 closed

Test has failed if the measured values are greater than:

N.C. S.F.C
 100 μA 500 μA
 300 μA (U.L. requirements)

Electrical diagram for Enclosure Leakage Current Test



7.1.3.3.2 Patient Leakage Current Test

This test performs a leakage current test under single fault conditions (S.F.C.) dependent of domestic power outlet with 115 or 230 V AC as source into the floating inputs.

In any case, the leakage current is measured from Input Jack, of unit under test, to ground.

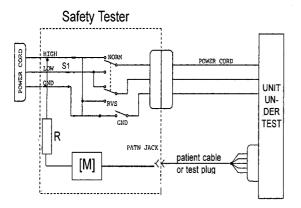
For testing the ECG input, a patient cable, with all leads connected together, is used.

Connect the unit under test to your Safety Tester.

- Referring to the electrical diagram, measurements have to be done under following conditions
- * Polarity switch NORM and RVS
- * GND switch GND closed
- * S1 closed

Test has failed if the measured values are greater than 50 $\,\mu A$

Electrical Diagram for Patient Leakage Current Test



For protection of the test person the following values of resistor R may be used:

Typ BF 22 kOhm (120 to 130 V) 47 kOhm (220 to 240 V) Typ CF 100 kOhm (220 to 240 V)

7.2 Maintenance, cleaning, disinfection

CardioSmart maintenance, cleaning, disinfection is performed in accordance with the CardioSmart or CardioSmart ST User's Manual, Chapter 11, "Cleaning, disinfection and maintenance", as applicable.

Applications requiring extensive recordings may result in deposits on the thermal array printhead which normally do not, however, have any adverse effect on the printing quality. This can be removed with a soft, fluff-free cloth soaked in an alcohol-based cleaning agent (e.g., surgical spirit).

8. Parts Lists

Part Number	Description CardioSmart		
101 116 01 101 116 02 101 116 03 101 116 04 101 116 05 101 116 06 101 116 07	CardioSmart CardioSmart CardioSmart CardioSmart CardioSmart CardioSmart CardioSmart	(int.) (USA) (russ.) (int), (russ), (Europe2) (Europe2)	Basic unit without Pump Basic unit without Pump Basic unit without Pump Basic unit with Pump Basic unit with Pump Basic unit without Pump Basic unit with Pump
CardioSmart ST			
101 116 10	CardioSmart ST	(int.)	Basic unit Stress Test without Pump
101 116 11	CardioSmart ST	(int.)	Basic unit Stress Test with Pump
101 116 12	CardioSmart ST	(USA.)	Basic unit Stress Test without Pump
101 116 13	CardioSmart ST	(USA.)	Basic unit Stress Test with Pump
101 116 14	CardioSmart ST	(russ.)	Basic unit Stress Test without Pump
101 116 15	CardioSmart ST	(russ)	Basic unit Stress Test with Pump
101 116 16	CardioSmart ST	(Europe 2.)	Basic unit Stress Test without Pump
101 116 17	CardioSmart ST	(Europe 2.)	Basic unit Stress Test with Pump
101 116 18	CardioSmart ST	(ASIA)	Basic unit Stress Test without Pump
101 116 19	CardioSmart ST	(ASIA)	Basic unit Stress Test with Pump

User Manual CardioSmart:

227 435 15	User Manual CardioSmart (d) V 1.1
227 435 16	User Manual CardioSmart (e) V 1.1
227 435 17	User Manual CardioSmart (f) V 1.1
227 435 41	User Manual CardioSmart (d) V 1.3
227 435 42	User Manual CardioSmart (e) V 1.3
227 435 43	User Manual CardioSmart (f) V 1.3

227 435 45	User Manual CardioSmart (i) V 1.3
227 435 46	User Manual CardioSmart (sp) V 1.3
227 43518	User Manual CardioSmart (USA) V 1.3
227 435 52	User Manual CardioSmart (e) for UK V 1.3
227 435 53	User Manual CardioSmart (f) for BeneluxV 1.3
227 435 58	User Manual CardioSmart (sw) V 1.3

User Manual CardioSmart ST:

227 465 01	User Manual Cardio Smart ST (d) V. 1.2
227 465 02	User Manual Cardio Smart ST (e) V. 1.2
227 465 03	User Manual Cardio Smart ST (f) V. 1.2
227 465 11	User Manual Cardio Smart ST (d) V. 1.3
227 465 12	User Manual Cardio Smart ST (e) V. 1.3
227 465 13	User Manual Cardio Smart ST (f) V. 1.3
227 465 15	User Manual Cardio Smart ST (i) V. 1.3
227 465 16	User Manual Cardio Smart ST (sp) V. 1.3
227 465 24	User Manual Cardio Smart ST (US) V. 1.3
227 465 24	User Manual Cardio Smart ST (russ) V. 1.3
227 465 32	User Manual Cardio Smart ST (e) for UK V. 1.3
227 465 33	User Manual Cardio Smart ST (f) for Benelux V. 1.3
227 465 38	User Manual Cardio Smart ST (f) for Benelux V. 1.3
227 465 42	User Manual Cardio Smart ST (sw) V. 1.3
227 465 38	User Manual Cardio Smart ST (sw) V. 1.3
227 465 42	User Manual Cardio Smart ST (asia) V. 1.3
227 435 11	Service Manual .d/e, 101116 Cardiosmart

Housing / Driving unit

Unter -case shell
Rubber foot
Battery cover
Upper case with keypad (russ)
Upper case with keypad (Int)
Upper case with keypad (USA)
Upper case with keypad (Europe 2)
Upper case with keypad ST (Int)
Upper case with keypad ST (Russ)
Upper case with keypad ST (Europe2)
Upper case with keypad ST (US)
Upper case with keypa ST (ASIA)
Handle
Drive Flap
Code reader

303 442 79	Motor
914 326 69	Microswitch
432 523 54	Stop for Microswitch
801 777 62	Screw for Stop
432 522 05	Plate for Driver Flap
504 657 60	Tinplate
929 166 45	Luer- connection kit (female)
929 166 54	Luer-cap

Electronic components / pcb's

929 166 40	Line filter with fuse holder
914 325 94	Rocker switch
303 442 71	Comb
303 442 70	Battery
388 029 10	pcb.Printhead connection
388 028 14	pcb. Power Supply
912 084 37	FuseT 4 A TR5
912 084 35	FuseT 1,25 A
912 084 04	FuseT 0,25 A
912 084 14	FuseT 0,5 A
388 028 12	pcb. Control (usable up to V 1.1)
389 004 05	Exchange pcb. Control (usable up to V 1.1)
303 446 18	pcb. Control ST (compatible for all CardioSmarts)
389 004 16	Exchange pcb. Control ST (compatible for all CardioSmarts)
929 165 73	Battery 3 V 0,8 Ah
303 442 91	Pump 12 V (Standard)

Display-Modul Graphics

235 066 01	CardioVision Graphics -Module for CardioSmart
235 066 02	CardioVision Graphics -Module for CardioSmart(USA)
388 028 87	pcb Mother board
388 028 11	pcb digital Display
930 117 17	LCD-Graphics Display
303 443 1	Upper-Case Part
303 442 80	Joint
432 522 01	Display Bottom Part
423 203 04	Insulation

Display-Modul Text

235 06 701	CardioVision Text Display-Modul for CardioSmart
235 067 02	CardioVision Text Display-Modul for CardioSmart (USA)
388 028 88	pcb. Mother board
303 442 87	LCD Modul
432 522 03	Display Top Part
432 522 04	Display Bottom Part
931 098 80	Instrument Bag for CardioSmart, nylon material, with pockets for accessories
Connectioncable (for CardioSmart)

223 330 04	Connection cable M(L)700 - C'Smart(ST) 5m lang
223 362 03	Connection cable 5 m long for
	CardioSmart to PC

223 366 04 Connection cable EC1200-CardioSmart(ST) 5m long 223 378 01 Connection cable for ECG- Transmission CardioSmart to Modem ELSA,9 pin.,3m long Connection cable for ECG- Transmission 223 378 02 CardioSmart to Modem Multitech 25 pin.,3m long

Connectioncable (Only for CardioSmart-ST)

223 362 04	Connection cable EC(B)560/561-C'Smart ST 5m long
223 380 02	Connection cable ERG900(L) - C'Smart ST 5m long
223 368 02	Connection cable TM400AC - C'Smart ST 5m long
223 390 03	Connection cable T2000-CardioSmart ST 5m long,
	(RS232 to RS 232)
384 017 67	Upgrade Interface Kit T 2000 (RS 422 to RS 232)
	—> CardioSmart for 230 V
384 017 68	Upgrade Interface Kit T 2000 (RS 422 to RS 232)
	—> CardioSmart für 115 V

9. Technical Specifications

For operation of the CardioSmart it is necessary to plug in one CardioProm module and one of the two available displays. The following technical specifications apply to all CardioSmart versions.

Recording

direct recording of waveforms and alphanumeric characters with rectangular coordinates by means of thermal-array printhead printing on thermosensitive paper.

- recording channels: 3 or 6, 12 in automatic mode; overlapping
- * space between baselines3 channels: 62 mm (arrhythmia)

6 channels: 31 mm (manual) 12 channels: 16 mm (auto.)

- * writing width 200 mm max.
- * annotation of device settings, date, time of day and patient name, if entered, in margin of recording strip
- with appropriate software module documentation of analysis results and report in each mode on separate pages
- resolution of the recording:
 vertically
 8 dots/mm
 horizontally
 25 μm at 25 mm/s

Chart paper

Marquette Hellige CONTRAST[®] Z-fold pad, 150 pages per pad, equivalent to a chart length of 45 m

paper width 210 mm or 8.5 in. (US format) sheet length 300 mm or 11 in. (US format)

To prevent debris from collecting on the printhead, use the Marquette Hellige CONTRAST chart paper only!

Chart transport

- * paper speed 5-25-50 mm/s (key-selectable) error limits at 25 and 50 mm/s typically ±1% at 5 mm/s ±10% max.
- when supply of chart paper is depleted, recorder switches off and sounds an alarm; the last pages of the pad bear a red stripe in the margin

Membrane keypad

membrane keys with tactile feedback

- * function keys for all important routine operations
- * alphanumeric keypad for entry of texts

Display

alphanumeric LCD, 2 x 40 characters, contrast adjustable, or

graphics display for 24 x 40 characters, contrast adjustable

resolution of 320 x 240 pixels, backlit

Indicators (LEDs)

for mains supply, battery charge level and start/stop function

Lead selection

manual selection of individual lead groups or automatic sequencing of lead groups

* lead programs (c):

EINTHOVEN, GOLDBERGER, WILSON, NEHB, CABRERA lead sequence, custom lead programs in manual mode

Automatic functions

assisting and facilitating device operation:

- * automatic amplifier blocking
- automatic lead sequencing, paper feed, calibration (c)
- * report formatting (**c**)
- * automatic baseline adjustment
- * anti-drift system compensating for polarization voltage fluctuations (**c**)

Detection of pacing pulses

- * pulse duration between 0.1 and 2.5 ms
- * marks irrespective of pulse polarity
- * pulse amplitude between ±5 mV and ±700 mV

Heart-rate display

derivation of the heart rate from all ECG signals

- * display range 30 to 300 BPM
- display update with every heart beat, max. every 2
 s

Signal inputs

isolated patient signal input, type CF according to IEC, high-voltage protection for all lead connections and Nelectrode connection, interference compensation via neutral electrode (N), monitoring for detection of open leads

- * electrode connections for R, L, F, N, C1 to C6, Nax, Nst and Nap (=C4)
- * input impedance for differential signals applied between any two electrode connections >10 M Ω for 10 Hz
- * input impedance for common-mode signals referred to N >50 M Ω for up to 60 Hz
- * dynamic range for differential signals between any two electrode connections for AC voltage ±10 mV, for superimposed DC voltage (polarization voltage) ±600 mV
- * dynamic range for common-mode signals referred to N±1V, referred to chassis 263 V AC voltage (rms)
- * quiescent input current via any electrode connection for 1-k Ω termination referred to N <50 nA
- patient leakage current (rms values) according to IEC class CF: under normal conditions <10 µA, in single-fault condition (e.g., patient in contact with line voltage) <20 µA
- non-destructive range for lead-electrode connections and the N-connection referred to N ±50 V, referred to chassis ±1500 V
- pulse voltage resistance of all lead-electrode connections and of the N-connection referred to chassis (e.g., defibrillation) 5000 V
- monitoring of each electrode for disconnection: R,
 L, F, N, C1, C2, C3, C4, C5, C6, Nap, Nax, Nst
 audible alarm signal upon program start

Data interface

one serial RS 232 interface for exchange of data with adapted peripherals and software handshake

RS 232 interface (standard V.24 interface):

- * input voltage range ±15 V max.
- * output voltage range ±5 V min.
- * ESD interface protection for up to ±10 kV

Remote start

remote start connection for paper feed (irrespective of selected operating mode), external make contact referred to chassis via circuit reference:

- * source impedance $R_i < 300 \Omega$
- dwell of contact >100 ms
- * non-destructive load ±10 V
- * ESD interface protection up to ±10 kV max.

Pin assignment of data port

- 2 RXDE
- 3 TXDE
- 5 circuit reference
- 8 remote start

Signal transmission

Patient signal input to recording

after lead formation and digitization simultaneous transmission of all electrode signals to the digital processing system; muscle filter, AC filter, pacing pulse identification, automatic or manual sensitivity adjustment, automatic baseline adjustment and drift compensation by means of the anti-drift system (A.D.S.) can be enabled or disabled simultaneously for all channels; digital output of processed signals via thermal-array printhead

- low cut-off frequency (-3-dB limits) 0.08 Hz, equivalent to a time constant of 2.04 s
- high cut-off frequency (-3-dB limits)
 in Auto and manual modes: 150 Hz (IEC/AHA)
 in Arrhy mode: 100 Hz (IEC)
- * signal sampling rate 1000/s
- * resolution, referred to the input, 5 μ V
- * output rate to recorder 2000/s
- for all leads adjustment of sensitivity in four steps:
 40-20-10-5 mm/mV
- with muscle filter (low-pass characteristic) switched on, 3-dB drop of the amplitude frequency response at approx. 35 Hz or 20 Hz
- with AC filter switched on, identification and compensation of periodic 50 or 60-Hz frequency components (depending on recorder model: attenuation > 40 dB)
- * non-linear distortion below values specified in IEC and AHA recommendations
- coincidence error limits between any two channels
 ±0.5 mm
- identification of pacing pulses in C2 or other Cleads and marking in all channels for signals referred to patient input: duration + 0.1 ms, amplitude > 5 mV
- * noise in the signal-transmission path below values specified in IEC and AHA recommendations: $\leq 2.5 \ \mu V \ rms$
- common-mode rejection for 50 or 60-Hz signals (depending on CardioSmart model) with AC filter switched on > 140 dB

ECG calibration

automatic recording of a defined voltage step, valid for all channels

calibration voltage of 1 mV, referred to ECG signal input

pulse width depending on paper speed 25 mm/s 5 mm 50 mm/s 10 mm 5 mm/s 1 mm

Automatic sensitivity adjustment of ECG signals

automatic adaption of the signal gain in dependence of the incoming signal; highest amplitude of a lead group or of all leads determines gain

- automatic adjustment range 5 to 40 mm/mV
- amplitude range (6 channels) 18 to 31 mm

Baseline

automatic adjustment of the baseline to the optimal recording range, in dependence of the signal amplitude

Anti-Drift System (A.D.S.)

automatic compensation of baseline fluctuations caused by polarization voltage fluctuations at the lead electrodes (recording delay 4.2 s)

ECG storage

- in automatic mode storage of up to 45 ECGs
- stored ECGs can be deleted (individually or all in one pass), printed, transferred or the patient data can be modified
- when memory is full user is informed of the possible actions

Blocking

rapid charge reversal of the coupling capacitors in the preamplifiers after electrode application

Electrode monitoring

audible and visual indication on the LCD of disconnected electrodes or line break; each single electrode is monitored

Text input

patient and user data as well as comments can be entered via the panel keyboard and are annotated on the recording strip

Copy function

in the automatic mode, after ECG recording, copies of the ECG can be printed from memory and/or transferred to a connected PC (c)

Test

automatic performance test upon power up, including verification of the signal path starting at the signal input

stored test data for demonstration of the device functions

Power

from the power line or from a built-in rechargeable battery, automatic switchover; automatic battery charging during line-power operation; no recording when battery depleted or missing

Line-power operation

instrument design in protection class I according to IEC 601-1, internally powered equipment

rate *	ed voltage range operating voltage range	220 to 240 198 to 264		Operational readiness			
		49 to 65	Hz	after successful selftest within 10 s of power-up			
*	rated current	0.16	A				
	fuse 2 x T 0.25 A, 5 x 20			Operating position			
rate	ed voltage range	110 to 120	V	horizontal			
*	operating voltage range	99 to 132	-				
		49 to 65		Environment			
*	rated current	0.32	A				
	fuse 2 x D 500 mA, 3 A-G			Operation			
*	power consumption typically:			 * ambient temperature between +10 and +40 °C 			
	during battery charging	15	W				
	device turned on	13	W	* rel. humidity between 25 and 95%			
*	max. power consumption	28	W	* atmospheric pressure between 700 and 1060 hPa			
Bat	tery-power operation			Storage and transport			
*	battery type nickel cadmium			* ambient temperature between -30 and +60 °C			
*	note d la otto nove lto no	10		(also with battery)			
	rated battery voltage	18	V	* rel. humidity between 25 and 95%			
*	rated battery capacity	1.4	Δh	Tel. Humidity between 20 and 30 %			
	Taled ballery capacity	1.4		* atmospheric pressure between 500 and 1060 hPa			
*	fully charged battery sufficient for	•					
	matic ECG recordings, if device is only for	s switched or	ו	Case dimensions			
	recording			* width 370 mm			
*	battery charging time			* height 95 mm			
	approx. 4 hours						
				* depth 320 mm (incl. handle)			
*	(min. charging time for recording ECG 10 min)	of one autom	Weight				
*	battery life approx. 2 to 3 years, re	eplacement b	ру	CardioSmart with battery and text display approx. 5.3			
	service technician only			kg CardioSmart with battery and graphics display approx.			
*	battery for built-in clock: lithium ba approx. 5 years, replacement by s cian	•	i-	5.6 kg			

CardioSmart ST

For operation of the CardioSmart ST it is necessary to plug in one CardioProm module and one of the two available displays. The following technical specifications apply to all CardioSmart ST versions.

Recording

direct recording of waveforms and alphanumeric characters with rectangular coordinates by means of thermal-array printhead printing on thermosensitive paper.

- recording channels: 6, 12 in automatic mode; overlapping
- space between baselines6 channels: 31 mm (manual)

12 channels: 16 mm (auto.)

- writing width 200 mm max.
- annotation of device settings, date, time of day and patient name, if entered, in margins of recording strip
- with appropriate software module documentation of analysis results and report in each mode on separate pages
- * resolution of the recording: 8 dots/mm vertically horizontally 25 µm at 25 mm/s

Chart paper

HELLIGE CONTRAST® Z-fold pad, 150 pages per pad, equivalent to a chart length of 45 m

paper width 210 mm or 8.5 in. (US format) sheet length 300 mm or 11 in. (US format)

To prevent debris from collecting on the printhead, use the HELLIGE CONTRAST chart paper only!

Chart transport

- paper speed 5 - 25 - 50 mm/s (key-selectable) at 25 and 50 mm/s typically ±1% error limits at 5 mm/s ±10% max.
- when supply of chart paper is depleted, recorder switches off and sounds an alarm; the last pages of the pad bear a red stripe in the margin

Membrane keypad

membrane keys with tactile feedback

- function keys for all important routine operations
- alphanumeric keypad for entry of texts

Display

graphics display for 24 x 40 characters, contrast adiustable

resolution of 320 x 240 pixels, backlit

Indicators (LEDs)

for mains supply, battery condition and start/stop function

Lead selection

manual selection of individual lead groups or automatic sequencing of lead groups

lead programs (c):

EINTHOVEN, GOLDBERGER, WILSON, NEHB, CABRERA lead sequence and custom lead programs in manual and stress test mode

Automatic functions

assisting and facilitating device operation:

- * automatic amplifier blocking
- * automatic lead sequencing, paper feed, calibration (**c**)
- * report formatting (c)
- * automatic baseline adjustment
- * anti-drift system compensating for polarization voltage fluctuations (**c**)

Detection of pacing pulses

- * pulse duration between 0.1 and 2.5 ms
- * marks irrespective of pulse polarity
- * pulse amplitude between ±5 mV and ±700 mV

Heart-rate display

derivation of the heart rate from all ECG signals

- * display range 30 to 300 BPM
- display update with every heart beat, max.
 every 2 s

Signal inputs

isolated patient signal input, type CF according to IEC, high-voltage protection for all lead connections and N-electrode connection, interference compensation via neutral electrode (N), monitoring for detection of open leads

 * electrode connections for R, L, F, N, C1 to C6, Nax, Nst and Nap (=C4)

- * input impedance for differential signals applied between any two electrode connections >10 $M\Omega$ for 10 Hz
- * input impedance for common-mode signals referred to N >50 M Ω for up to 60 Hz
- * dynamic range for differential signals between any two electrode connections for AC voltage ±10 mV, for superimposed DC voltage (polarization voltage) ±600 mV
- * dynamic range for common-mode signals referred to N±1V, referred to chassis 263 V AC voltage (rms)
- * quiescent input current via any electrode connection for 1-k Ω termination referred to N <50 nA
- patient leakage current (rms values) according to IEC class CF: under normal conditions <10 μA, in single-fault condition (e.g., patient in contact with line voltage) <20 μA
- non-destructive range for lead-electrode connections and the N-connection referred to N ±50 V, referred to chassis ±1500 V
- * pulse voltage resistance of all lead-electrode connections and of the N-connection referred to chassis (e.g., defibrillation) 5000 V
- * monitoring of each electrode for disconnection: R, L, F, N, C1, C2, C3, C4, C5, C6, Nap, Nax, Nst audible alarm signal upon program start

Data interface

one serial RS 232 interface for exchange of data with adapted peripherals and software handshake

RS 232 interface (standard V.24 interface):

* input voltage range ±15 V max.

- * output voltage range ±5 V min.
- * ESD interface protection for up to ±10 kV

Remote start (hardware)

remote start connection for paper feed (depending on selected operating mode), external make contact referred to chassis via circuit reference:

- * source impedance $R_i < 300 \Omega$
- * dwell of contact >100 ms
- non-destructive load ±10 V
- * ESD interface protection up to ±10 kV max.

Pin assignment of data port

2 RXDE

- 3 TXDE
- 5 circuit reference
- 8 remote start

Signal transmission

Patient signal input to recording

after lead formation and digitization simultaneous transmission of all electrode signals to the digital processing system; muscle filter, AC filter, pacing pulse identification, automatic or manual sensitivity adjustment, automatic baseline adjustment and drift compensation by means of the anti-drift system (A.D.S.) can be enabled or disabled simultaneously for all channels; digital output of processed signals via thermal-array printhead

* low cut-off frequency (-3-dB limits) 0.08 Hz, equivalent to a time constant of 2.04 s

- high cut-off frequency (-3-dB limits)
 in Auto and manual modes: 150 Hz (IEC/AHA)
 in stress test mode: 75 Hz (IEC)
- * signal sampling rate 1000/s
- * resolution, referred to the input, 5 μ V
- * output rate to recorder 2000/s
- for all leads adjustment of sensitivity in four steps:
 40-20-10-5 mm/mV
- with muscle filter (low-pass characteristic)
 switched on, 3-dB drop of the amplitude frequency
 response at approx. 35 Hz or 20 Hz
- with AC filter switched on, identification and compensation of periodic 50 or 60-Hz frequency components (depending on recorder model: attenuation > 40 dB)
- * non-linear distortion below values specified in IEC and AHA recommendations
- coincidence error limits between any two channels ±0.5 mm
- identification of pacing pulses in C2 or other Cleads and marking in all channels for signals referred to patient input: duration + 0.1 ms, amplitude > 5 mV
- * noise in the signal-transmission path below values specified in IEC and AHA recommendations: $\leq 2.5 \ \mu V \ rms$
- common-mode rejection for 50 or 60-Hz signals (depending on CardioSmart ST model) with AC filter switched on > 140 dB

ECG calibration

automatic recording of a defined voltage step, valid for all channels

calibration voltage of 1 mV, referred to ECG signal input

pulse	width	depending	on	paper	speed
-					

25 mm/s 5 mm 50 mm/s 10 mm 5 mm/s 1 mm

Automatic sensitivity adjustment of ECG signals

automatic adaption of the signal gain in dependence of the incoming signal; highest amplitude of a lead group or of all leads determines gain

- * automatic adjustment range 5 to 40 mm/mV
- amplitude range (6 channels) 18 to 31 mm

Baseline

automatic adjustment of the baseline to the optimal recording range, in dependence of the signal amplitude

Anti-Drift System (A.D.S.)

automatic compensation of baseline fluctuations caused by polarization voltage fluctuations at the lead electrodes (delay in recording: 4.2 s)

ECG storage

- in automatic mode storage of up to 45 ECGs
- stored ECGs can be deleted (individually or all in one pass), printed, transferred or the patient data can be modified

* when memory is full user is informed of the possible actions

Blocking

rapid charge reversal of the coupling capacitors in the preamplifiers after electrode application

Electrode monitoring

audible and visual indication on the LCD of disconnected electrodes or line break; each single electrode is monitored

Text input

patient and user data as well as comments can be entered via the panel keyboard and are annotated on the recording strip

Copy function

in the automatic mode, after ECG recording, copies of the ECG can be printed from memory and/or transferred to a connected PC (c)

Test

automatic performance test upon power up, including verification of the signal path starting at the signal input

stored test data for demonstration of the device functions

Power

from the power line or from a built-in rechargeable battery, automatic switchover; automatic battery charging during line-power operation; no recording when battery depleted or missing

Line-power operation

- instrument design in protection class I according to IEC 601-1
- rated voltage range * 220 to 240 V
- operating voltage range 198 to 264 V; 49 to 65 Hz rated current 0.16 A
- 2x slow-blow 0.25 A, 5 x 20 fuse
- 110 to 120 V rated voltage range
- operating voltage range 99 to 132 V: 49 to 65 Hz
- rated current 0.32 A 2 x D 500 mA, 3AG fuse
- power consumption typically: during battery charging 15 W device turned on 13 W
- max. power consumption 28 W

Battery-power operation

- rated battery voltage 18 V
- * rated battery capacity 1.4 Ah
- fully charged battery sufficient for up to 50 automatic ECG recordings, if device is switched on only for recording
- battery charging time approx. 4 hours
- (min. charging time for recording of one automatic ECG 10 min)
- battery life approx. 2 to 3 years, replacement by service technician only

battery for built-in clock: lithium battery, life of approx. 5 years, replacement by service technician

Operational readiness

after successful selftest within 10 s of power-up

Operating position

horizontal

Environment

Operation

- ambient temperature between +10 and +40 °C
- rel. humidity between 25 and 95%
- atmospheric pressure between 700 and 1060 hPa

Storage and transport

- ambient temperature between -30 and +60 °C (also with battery)
- * rel. humidity between 25 and 95%
- atmospheric pressure between 500 and 1060 hPa

Case dimensions

- width 370 mm
- 95 mm height
- 320 mm (incl. handle) depth

Weight

CardioSmart ST with battery and graphics display approx. 5.6 kg

10. Device Documents

The following documents are enclosed:

- Entire instrument mechanical specifications:

- Assembly drawing:		101 116 0119
- Entire instrument wiring sp	ecifications:	101 116 0107/1019 S Sheet 1
- Master Record Index: MRI V1.0 MRI V1.1 MRI V1.2 MRI V1.3		101 116 0103 S Sh. 2 101 116 0105 S Sh. 3 101 116 0105/1013 S Sheet 4 101 116 0107/1019 S Sheet 5,6
- PCB Control CS:		388 028 12 P Sh. 1/8 and Sheet 8/8 388 028 12 R Sh. 1/2 and Sheet 2/2
- PCB Control CS_S:		388 032 13 P Sh. 1/8 and Sheet 8/8 388 032 13 R Sh. 1/2 and Sheet 2/2
- PCB Power Supply CS:		388 028 14 P 388 028 14 R

Note on Master Record Index (MRI)

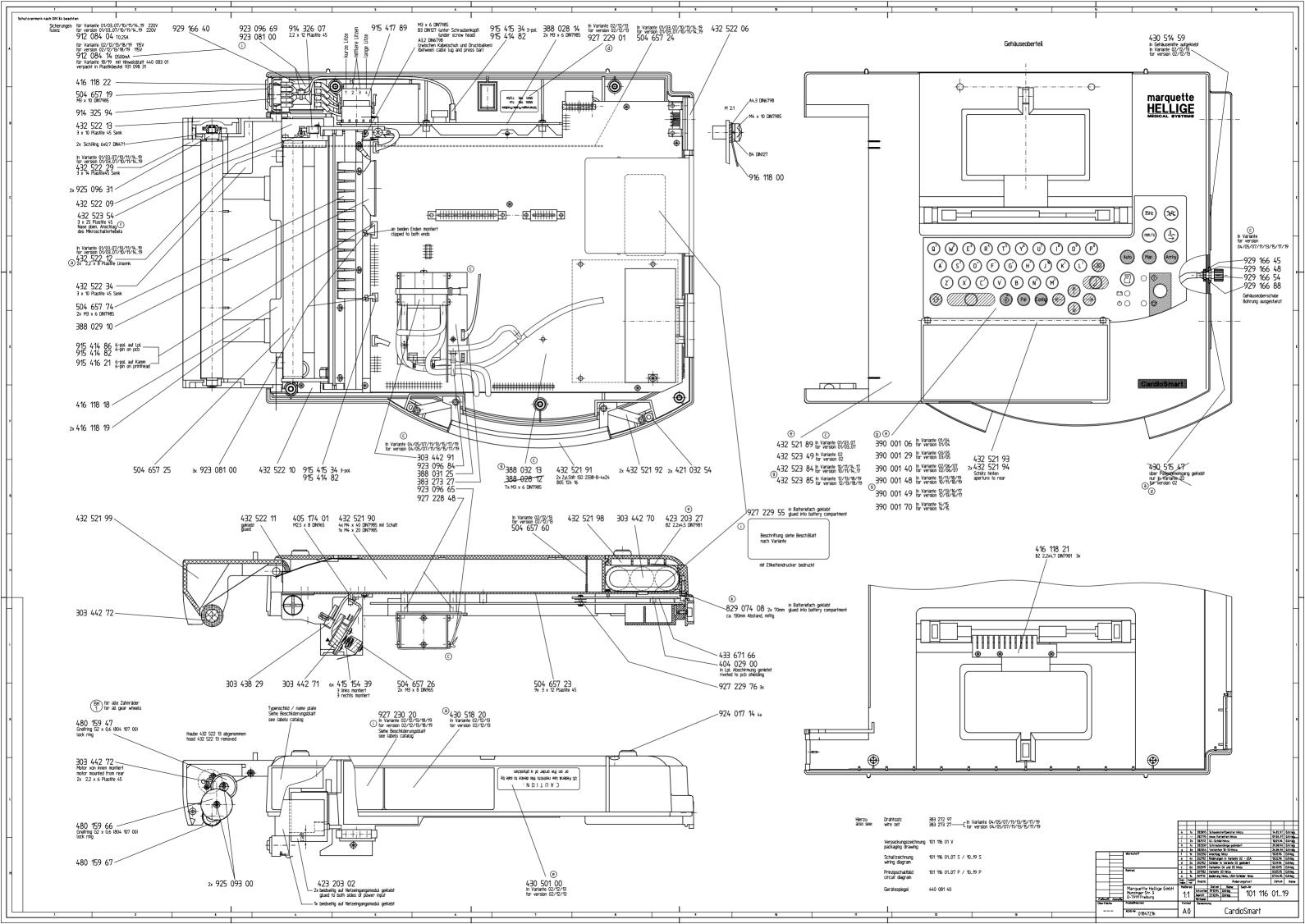
MRI	modified/new functions	PCB Control used
MRI V1.0	CardioSmart w/o remote start input Device types 101 116 0103 Device status V1.0	388 028 12, PCB Control CS
MRI V.1.1	CardioSmart with remote start input and optional suction pump Device types 101 116 0105 Device status V1.1	388 032 12, PCB Control CS_S
MRI V.1.1	CardioSmart with remote start input and optional suction pump Device types 101 116 0105 Device status V1.1	388 032 13, PCB Control CS_S
MRI V.1.2	CardioSmart ST with remote start input and optional suction pump Device types 101 116 1013 Device status V1.2	388 032 13, PCB Control CS_S
MRI V.1.3	CardioSmart with remote start input and optional suction pump, additional Regional models Device types 101 116 1013 Device status V1.2	388 032 13, PCB Control CS_S

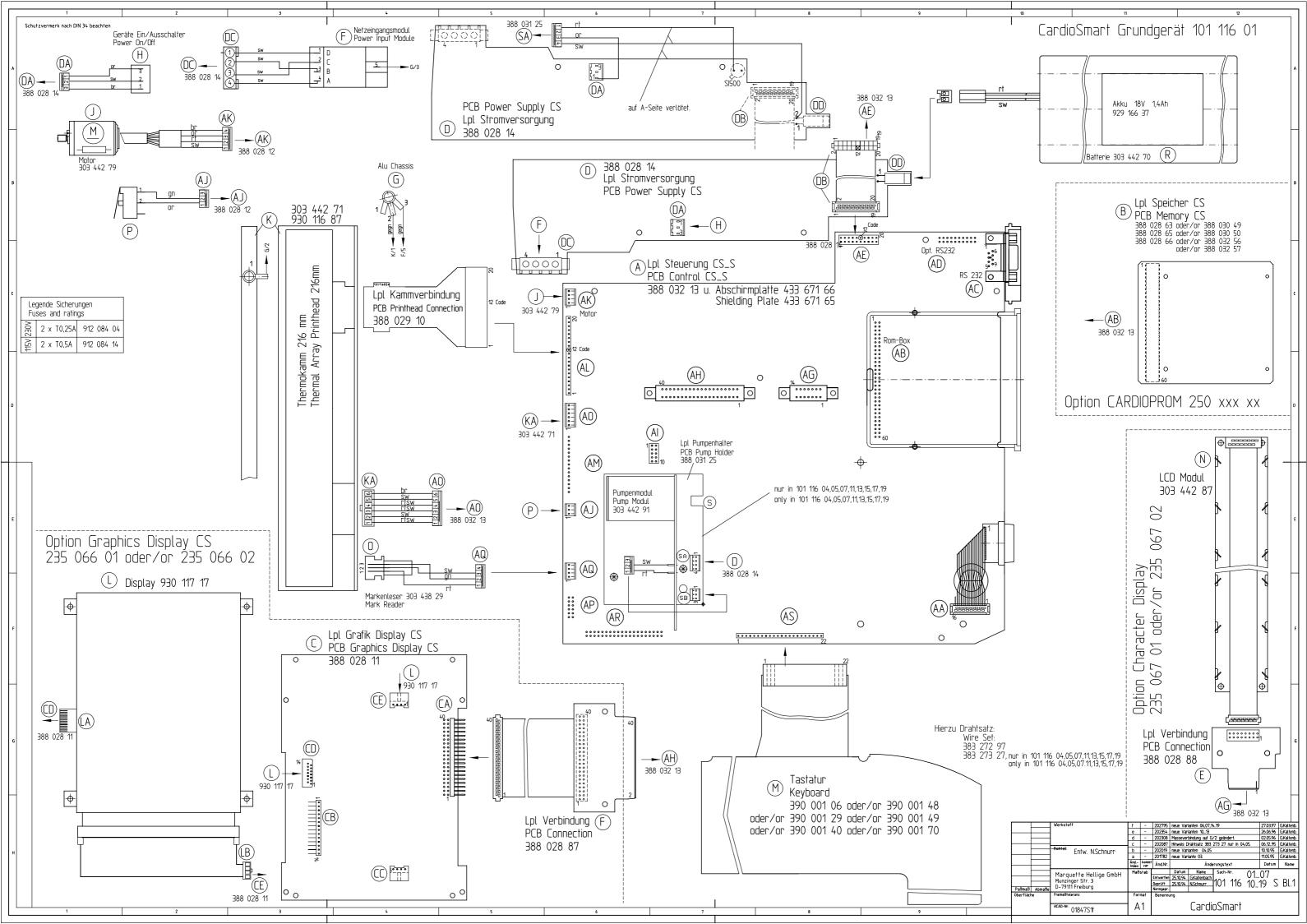
MRI V.1.3 CardioSmart ST with remote start input and optional suction pump, additional Regional models Device types 101 116 10...13 Device status V1.2

388 032 13, PCB Control CS_S

For reference numbers, compatibilities and correspondence with the respective versions of the device, please refer to the appropriate Master Record Index.

11. Appendix





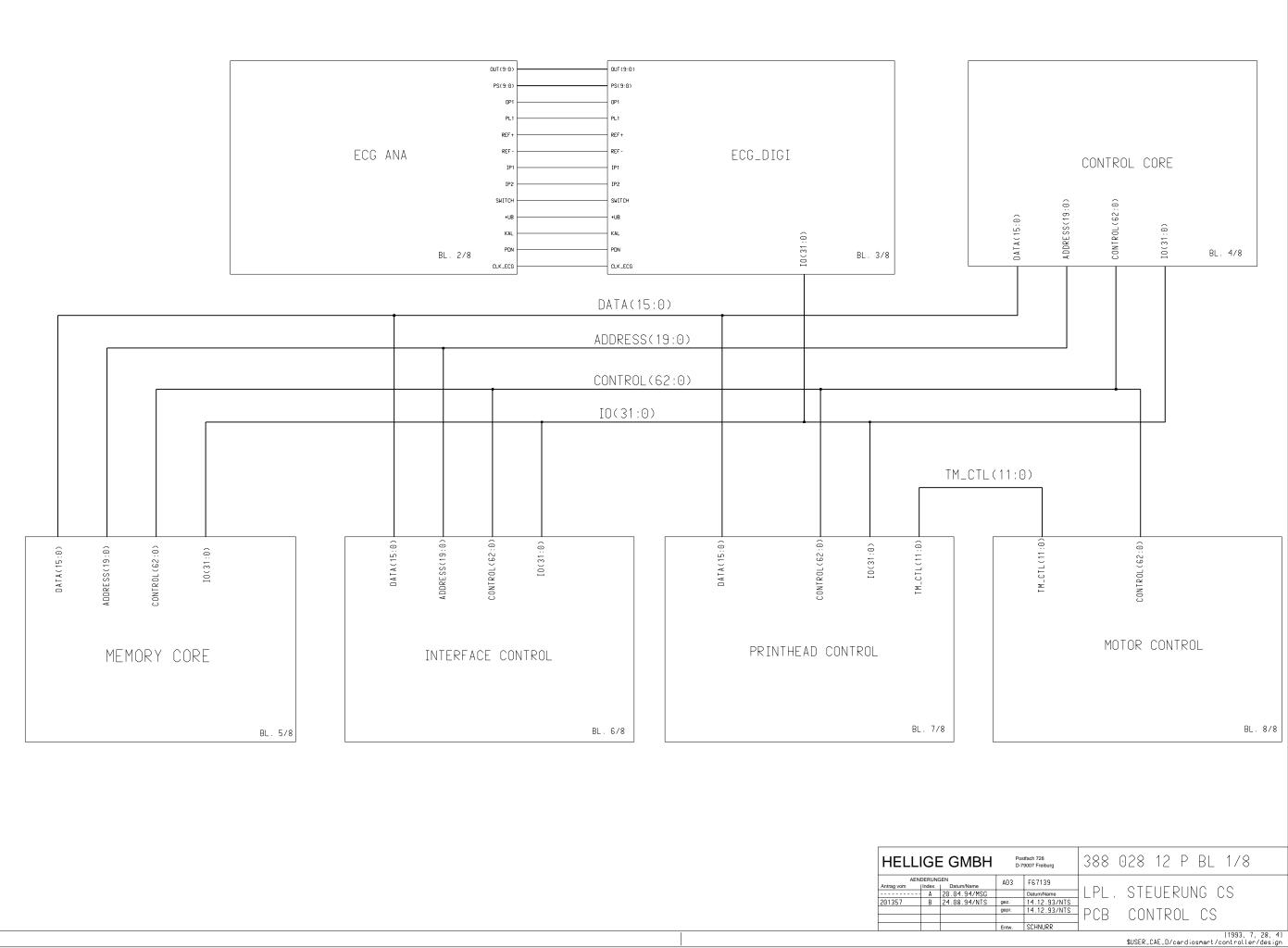
								3		4		
		1		2				3		4		
			Diese Tabelle d This table define		-	_						
A	Котро Сотро				Sach-I Part N		Index (Prod.)	Referenz Reference	•	tibel(Service) tible(Service)	in	Variante Device riation
	Steuer	ung CS	Lpl. Steuerung CS Ersatzteil-Nr. Austausch Nr.	PCB Control CS Spare Part No. Replacement No	-		Ι	A		E , F1 , H	(0103
	Stromv sorgun		Lpl. Stromvers- sorgung CS Ersatzteil-Nr. Austausch Nr.	PCB Power Supply CS Spare Part No. Replacement No		28 14	В	D			(0103
	Display	/S:	Cardio Vision Grapt		235 0	66 01						
	Grafik Display		Lpl. Grafik Display CS Ersatzteil-Nr. Austausch Nr.	PCB Graphics Display CS Spare Part No. Replacement No		28 11	D	C		С		
	oder /		Cardio Vision Text LCD Modul-CS		235 0 303 4							
						1	1					
			Werkstoff	ŀ								
Ξİ			ļ	ŀ	d	201999	lindex v	Lpl Steuerung a		20	.09.95	G.Kaltenb.
Ę,			ļ		c	201780		Lpl Steverung a			.05.95	G.Kaltenb.
ĕ			^{Rohteil} Entw.		b	201810		Lpl Steuerung a			.05.95	G.Kaltenb.
h, ¦					a	201747				20	.04.95	G.Kaltenb.
z			N.Schnurr		Änd komn Index vor	^{nt} Änd.Nr.		Änder	rungstext	[)atum	Name
schutzvermerk nach DIN 34 beachten	Раβтаβ	<u>م</u> لام م	HELLIGE GN Postfach 728 D-79007 Freibur		Maßstab	Entworfen Geprüft Normgepr.	17.01.95	Name G.Kaltenbach N.Schnurr	Sach-Nr. 101 11	6 010	3 S	Bl.2
Ĕŀ	Oberfläche	Abmaße	Freimaßtoleranz	<u>د</u>	Format	Benenn			<u>Dr</u>			
chutzve.			ACAD-Nr. 01847S2		A4		-			'd Index Version		
1 K			1 2.01.02			1						

		1		2					3			4	
			Diese Tabelle de This table define										
A	Kompon Compon					ach-Ni art No		Index (Prod.)	Referenz Referenci		ibel(Servici ible(Servic	in in	Variante Device Iriation
	Steuerur		Lpl. Steuerung CS Ersatzteil-Nr.	PCB Control C Spare Part No).	38_02		J	A		Н,І		0105
	oder /	or	Austausch Nr.	Replacement N		39 00							
в	Steuerur CS_S	-	Lpl. Steuerung CS_S Ersatzteil-Nr. Austausch Nr.	PCB Control CS_S Spare Part No Replacement N).	38 03: _ 39 00		В	A				0105
	Stromve		Lpl. Stromvers-	PCB Power		38 02			D				0105
	sorgung	CS	sorgung CS Ersatzteil-Nr. Austausch Nr.	Supply CS Spare Part No Replacement N).	- -	0 14	L	U				
-													
	Displays		Cardio Vision Grapt	nics	23	35 06	6 01						
	Grafik Display	CS	Lpl. Grafik Display CS Ersatzteil-Nr. Austausch Nr.	PCB Graphics Display CS Spare Part No Replacement N).	38 02 - -	8 11	D	C		С		
5													
	oder /		Cardio Vision Text		23	35 06	7 01						
			LCD Modul-CS		30)3 44:	2 87						
	Pumpenr	nodul:			ЭС)3 44	2 91						04,05
			Lpl. Pumpe	PCB Pumpe	38	38 02	9 18	В					04,05
E			Ersatzteil-Nr. Austausch Nr.	Spare Part No Replacement N		-							
-			Werkstoff		e		202498		3 028 12 van			03.09.96	G.Kaltenb.
-			Rohteil rate		d C		202354 202019	Varianten	rung neue Sac 04,05 hinzu.		2 13	25.06.96 09.10.95	G.Kaltenb. G.Kaltenb.
			^{Rohfeil} Entw.		b a		201999 201901		pl Steuerung : 88 028 14 von			09.08.95 09.08.95	G.Kaltenb. G.Kaltenb.
┢			N.Schnurr		Index	kommt vor	Änd.Nr.	Datur		rungstext		Datum	Name
	Paßmaß	Abmaße	HELLIGE G Munzinger Str. 3 D-79111 Freiburg	3	Maßs —		Entworfen Geprüft Normgepr.	11.05.95	Name G.Kaltenbach N.Schnurr	^{Sach-Nr.} 101 116	5 01(05 S	Bl.3
ľ	Oberfläche		Freimaßtoleranz		Forn		Benenn	^{ung} M	1aster	Record	d Inde	X	
			ACAD-Nr. 01847S3	2	A	4		Ċ	ardioS	mart V	/ersio	n 1.1	

				2					3		4		
			Diese Tabelle d This table defin				-		ın 1.2				
A		Komponente Component				ich-Nr irt No.		Index (Prod.)	Referenz Reference	kompatibel(S Compatible(S		in D	'ariante levice iation
		Steuerung CS_S	Lpl. Steuerung CS_S Ersatzteil-Nr.	PCB Control CS_S Spare Part No		8 032 _	2 13	C	A	В		010	5,1013
			Austausch Nr.	Replacement N		39 004	4 16						
B	3	Stromver- sorgung CS	Lpl. Stromvers- sorgung CS Ersatzteil-Nr. Austausch Nr.	PCB Power Supply CS Spare Part Nc Replacement N).	8 028 - -	3 14	C	D			010	5,1013
		Displays:	Cardio Vision Grap	hics	23	15 066	5 01					010	5,1013
		Grafik Display CS	Lpl. Grafik Display CS Ersatzteil-Nr. Austausch Nr.	PCB Graphics Display CS Spare Part Nc Replacement N).	8 028 - -	3 11	D	C	C		010	5,1013
		oder / or											
			Cardio Vision Text			15 067 13 442							0105
			LCD Modul-CS		50		. 07				יוטר		0105
		Pumpenmodul:			ЭС)3 442	2 91					04,0	5,11,13
	_		Lpl. Pumpe	PCB Pumpe	38	8 029	9 18	В				04,0	5,11,13
			Ersatzteil-Nr. Austausch Nr.	Spare Part No Replacement N		-							
1	E												
								1					
hten			Werkstoff										
4 beac			Rohteil Entw.										
DIN 3.			N.Schnurr		a Änd Index	- kommt vor	202713 Änd.Nr.	388 03	2 13 v. Index "B" aut Änderung			03.97 atum	G.Kaltent Name
Schutzvermerk nach DIN 34 beachten			HELLIGE C Munzinger Str. D-79111 Freibur	3	Mafis —	itab E	intworfen ieprüft		6 G.Kaltenbach	ach-Nr. ()1 116 /	0105 1013	S	Bl.4
zverm		Paßmaß Abmaß Oberfläche	Freimaßtoleranz	<u>ч</u>	Forn		lormgepr. Benenni	ung	 Master R				
Schut			ACAD-Nr. 0184754	-9	A	4			CardioSma			1.2	

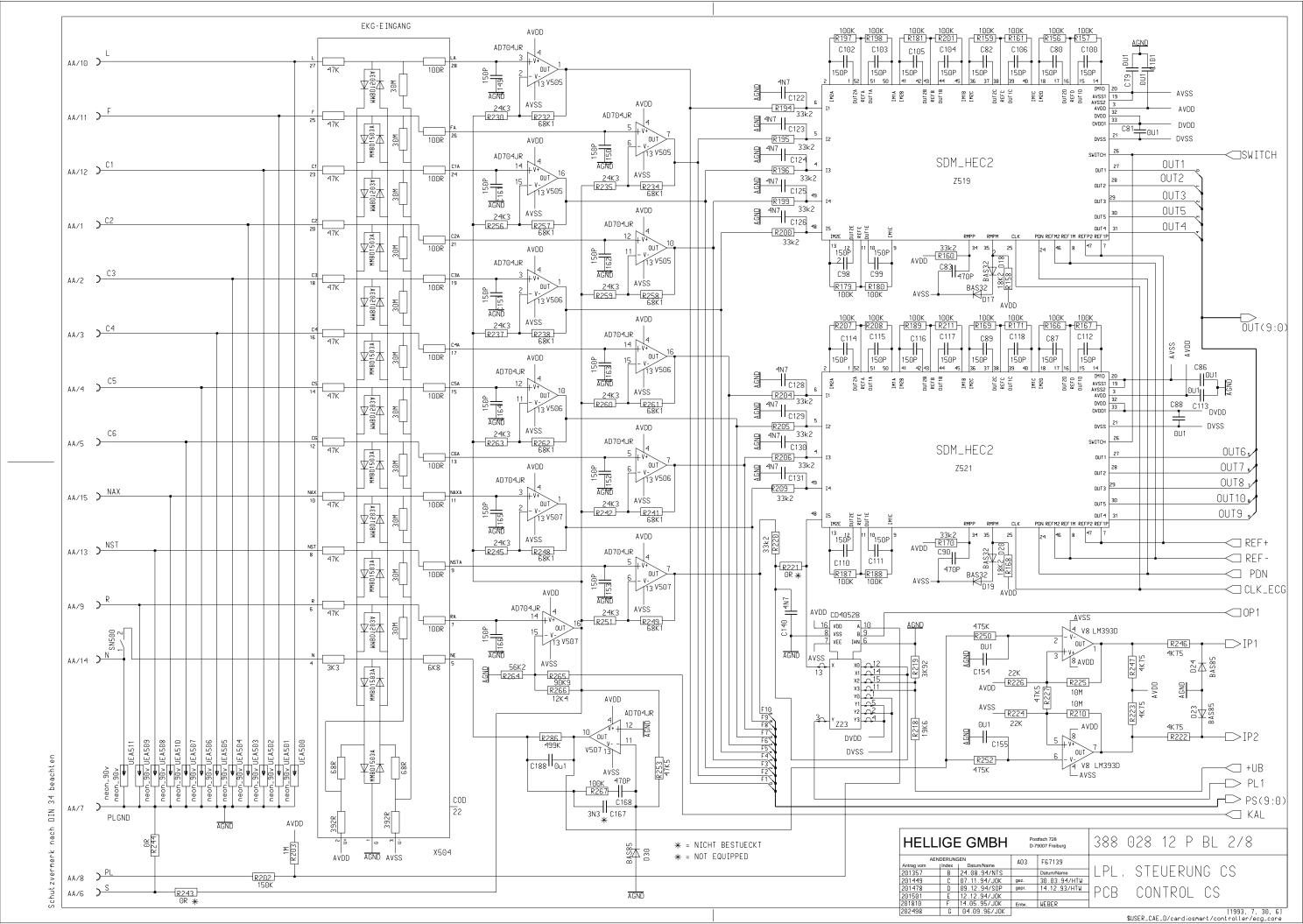
		1		2					3			4	
			Diese Tabelle This table defi	-	_		-					3	
A	Kompon Compon					ch-Nr rt No.		Index (Prod.)	Referenz Referenc		atibel(Servic atible(Servic	in	Variante Device riation
	Steuerui CS_S	ŋ	Lpl. Steuerung CS_S Ersatzteil-Nr.	PCB Control CS_S Spare Part No	D.	8 032		D	A		В,С	01()7,101 9
			Austausch Nr.	Replacement N	NO. 30	9 004	+ 16						
В	Stromve sorgung		Lpl. Stromvers- sorgung CS Ersatzteil-Nr. Austausch Nr.	PCB Power Supply CS Spare Part No Replacement N	כ.	8 028 - -	3 14	C	D			01(07,1019
-	Graphics	e Disola	N/S·										
			Cardio Vision Gra			5 066						307,10,1	
		er/or	Cardio Vision Gra		US) 23			_				2,13,18,19	
C	Grafik Display	CS	Lpl. Grafik Display CS Ersatzteil-Nr. Austausch Nr.	PCB Graphics Display CS Spare Part No Replacement N	כ.	8 028 - -	3 11	D	C		C	01()7,101 9
_	oder/or	Text [Displays : Cardio Vision Tex	ŀ	23	5 067	1 01					01,04,06	07
D	0	der∕or	Cardio Vision Tex		US) 23							02	
			LCD Modul-CS		30	3 442	2 87					01,02,04	,06,07
	Pumpenr	nodul:			30	3 442	2 91				04,05,	.07,11,13,1	15,17,19
E			Lpl. Pumpe	PCB Pumpe	38	8 029	9 18	В			04,05,	07,11,13,	15,17,19
			Ersatzteil-Nr. Austausch Nr.	Spare Part No Replacement N		-							
드			Werkstoff										
acht													
34 be			^{Rohteil} Entw.		a	-	202936	neuer In	dex Lpl Steuer	ung		17.06.97	G.Kaltent
h DIN			N.Schnurr		Index	kommt vor	Änd.Nr.			rungstext		Datum	Name
chutzvermerk nach DIN 34 beachten	Paßmaß	Abmaße	Marquette H Munzinger Str. D-79111 Freibur	3	Mafis —	E	intworfen ieprüft lormgepr.		Name G.Kaltenbach N.Schnurr	Sach-Nr. 101 1	01.0 16 101	07 19 S	Bl.5
zveri	Oberfläche		Freimaßtoleranz		Form		Benenni	^{''ng} N	1aster	Reco	rd Inde	<u>x</u>	
chut.			ACAD-Nr. 01847S	5a	A	4		Ċ	ardioS	mart	Versio	n 1.3	

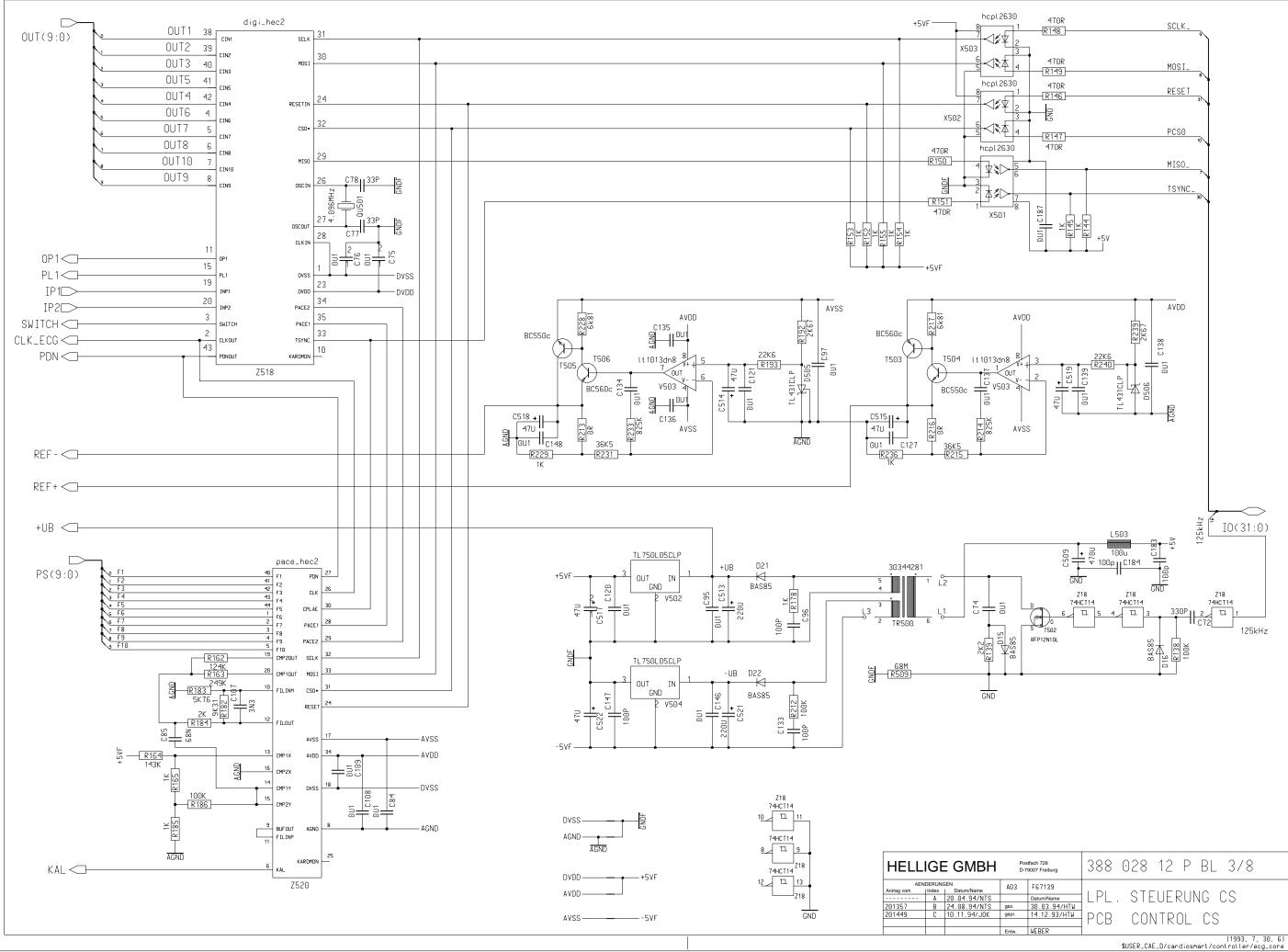
		1	2				3				4		
A		Diese Tabelle definiert die gültigen Konfigurationen des CardioSmart Version 1.3 This table defines the valid configurations of the CardioSmart Version 1.3											
	Referenzta	Referenztabelle der Geräte Versionen zu den zugehörigen CardioProm Software-Versionen											
	Geräte- Versioner	ı		-Versi	onen								
		V3.03.0c	V3.0d	\ \	V4.′	1	V4.11	۱ ۱	/4.2	\ \	/4.21		
	V1.0	X											
в	V1.1		X		Х		Х						
	V1.2		X				X		Х				
	V1.3										X		
		 X = vorge	esehene Verwendu	ingen,v	ollk	omptibel	,alle Funkti	onen entsp	prechend				
c		werd zur V korre Jer Geräte- un	rell können alle So en, jedoch stehen o (erfügung.Neue Fe espondierenden So d Software-Ve	dann be atures ftware ersione	estin der Vei en	nmte Fur Geräte rsionen	nktionen nic Versionen unterstützt	ht,oder nu werden nur t.	r eingesch • mit den	ränkt			
	Geräte- Version	Software- Version	Neue Gerä	te Funk	<tior< td=""><td>ien</td><td>Neue Si</td><td>oftware Fu</td><td>nktionen</td><td></td><td>atum</td><td></td></tior<>	ien	Neue Si	oftware Fu	nktionen		atum		
	V1.0	V3.0					CS-MI				2/94		
		V3.0a V3.0b					CS, CS-E, CS-I CS-M, CS-ME			12/94			
D		V3.0c						italienisch spanisch			02/95		
		V3.0d					Fernst russisc	art		05/95			
	V1.1		Fernstart Pumpe							0	19/95		
		V4.1					12SL-Programm Modem Speicherung 45EKGs CSI-Protokoll amerikanische Variante			08/96			
E	V1.2	V4.2	CardioSmai Ergometrie				Ergometrie		12/96				
		V4.11					Override Funktion			02/97			
	V1.3	V4.21	Gebietsvar	rianten			schwedisch			04/97		_	
		Werkstoff											
34 beachten		-											
, bea		Rohteil Entw.											
				Änd k	commt	Änd.Nr.		¥ . 1			D-+	N ¹	
ch D		N.Schnurr	Hellige GmbH	Index Mafist	VOL			Änderung Name Sa			Datum 07	Name	
Schutzvermerk nach DIN	Paßmaß Abmal	— Munzinger St — D-79111 Freih	r. 3 -	-			n 01.04.97 G.Kaltenbach 01.04.97 N.Schnurr 101 116		01.0 101	19 S	Bl.6		
zveri	Oberfläche	Freimaßtoleranz		Format		Benennu	ייי Mas	ster R					
Schut:		ACAD-Nr. 01847	/\$6_	A4		CardioSmart Vi							



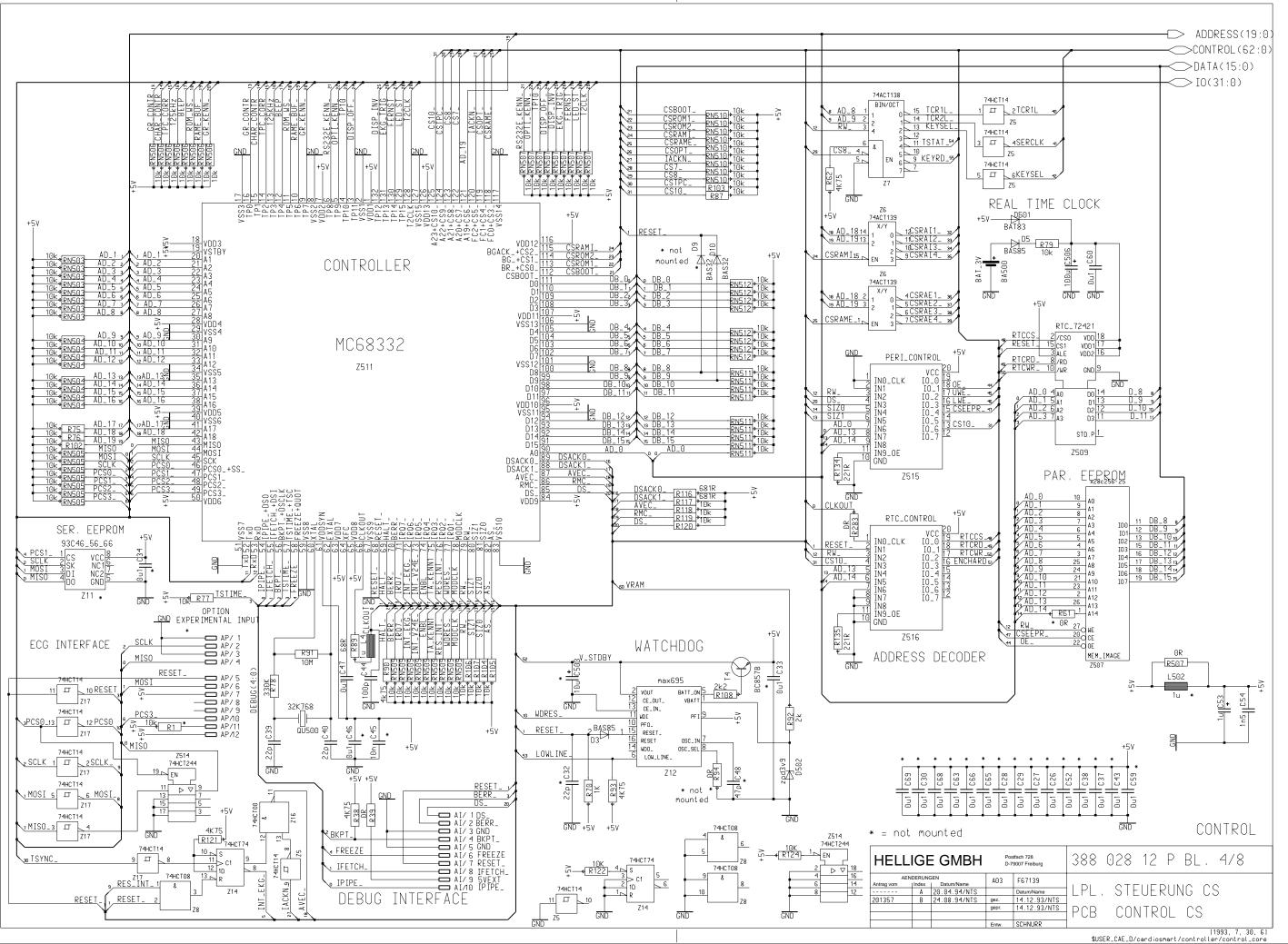
nach DIN 34 beachten Schut zvermerk

.

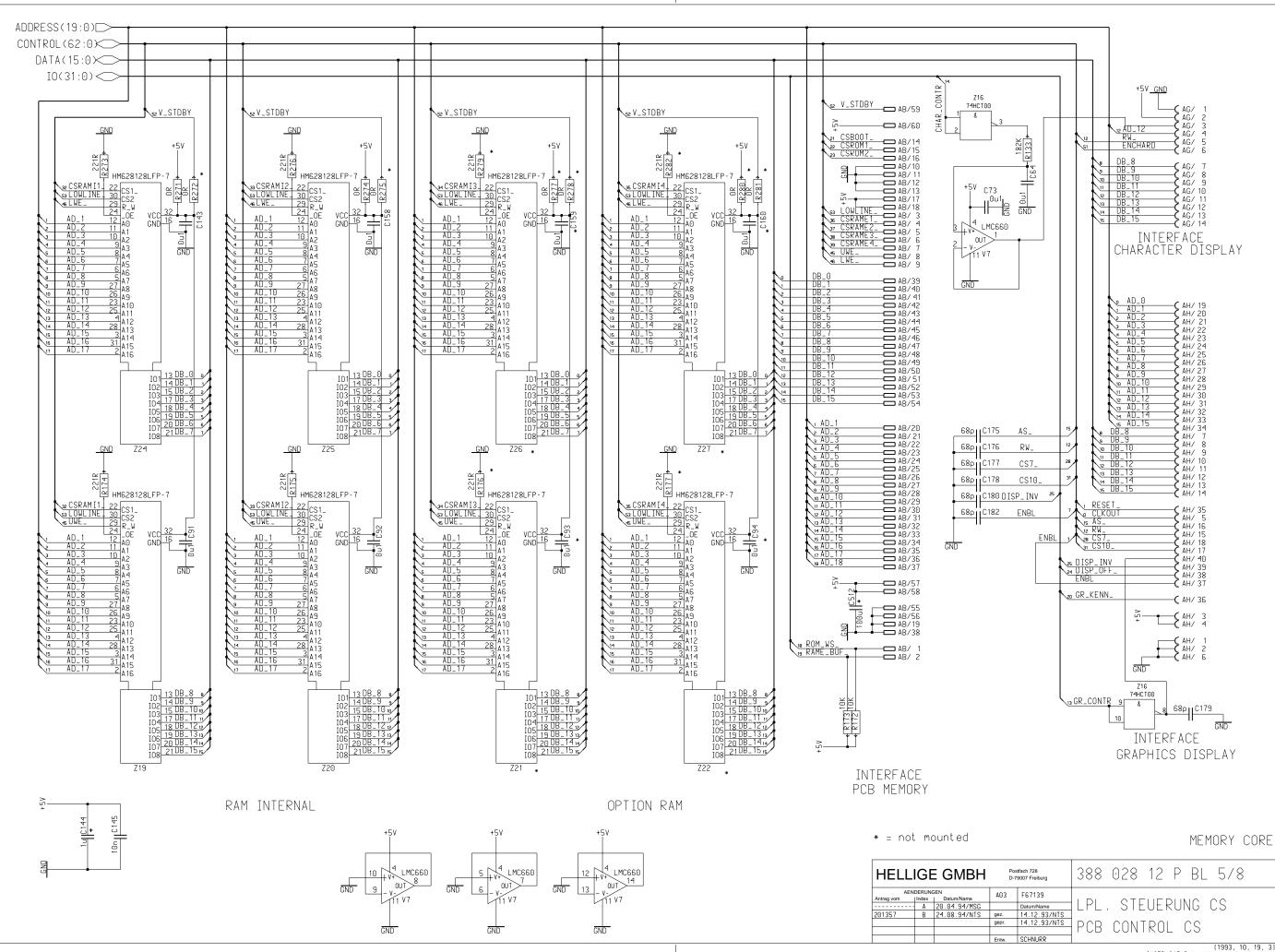




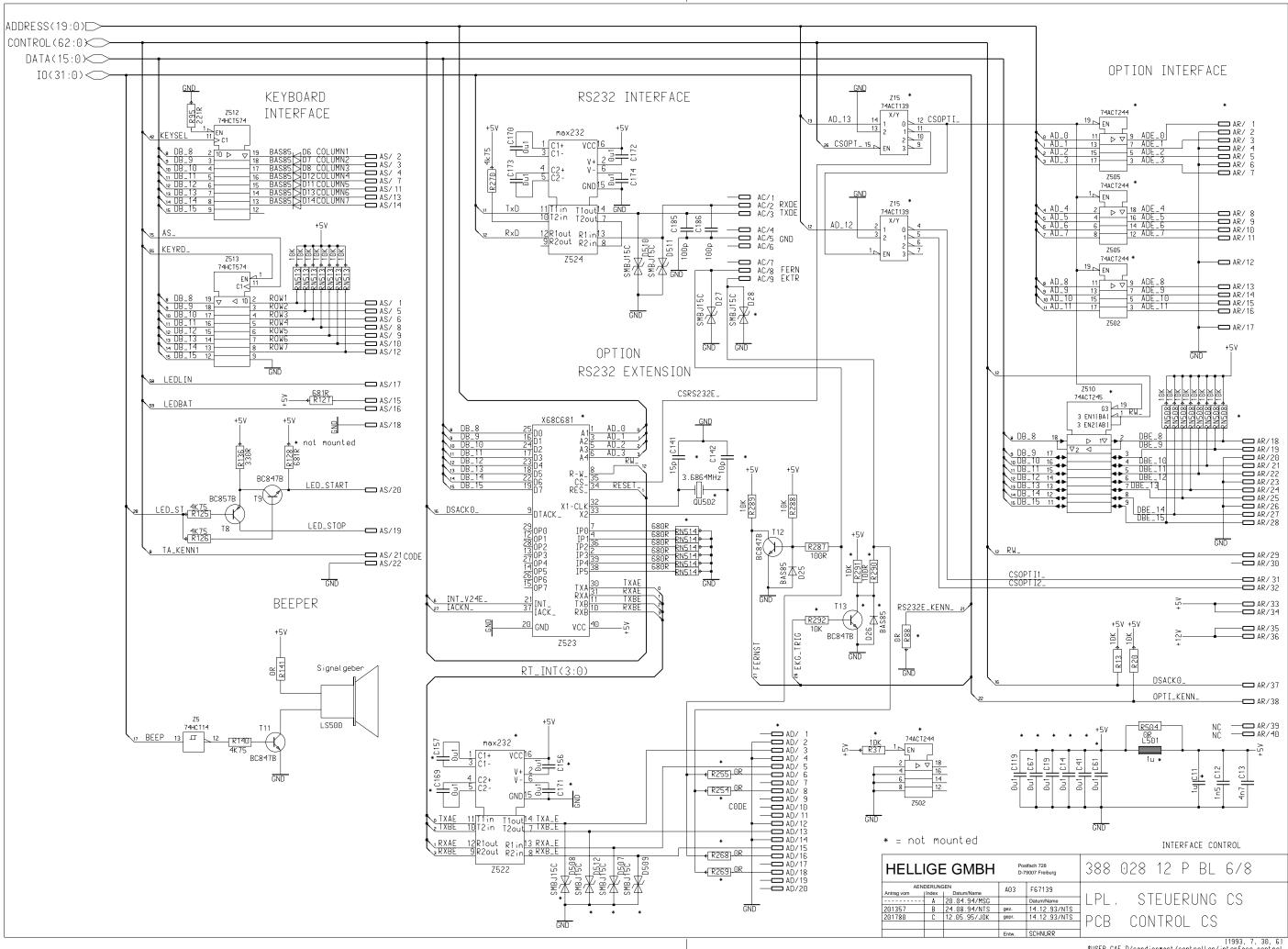
cht 34 DIN nach nut zver



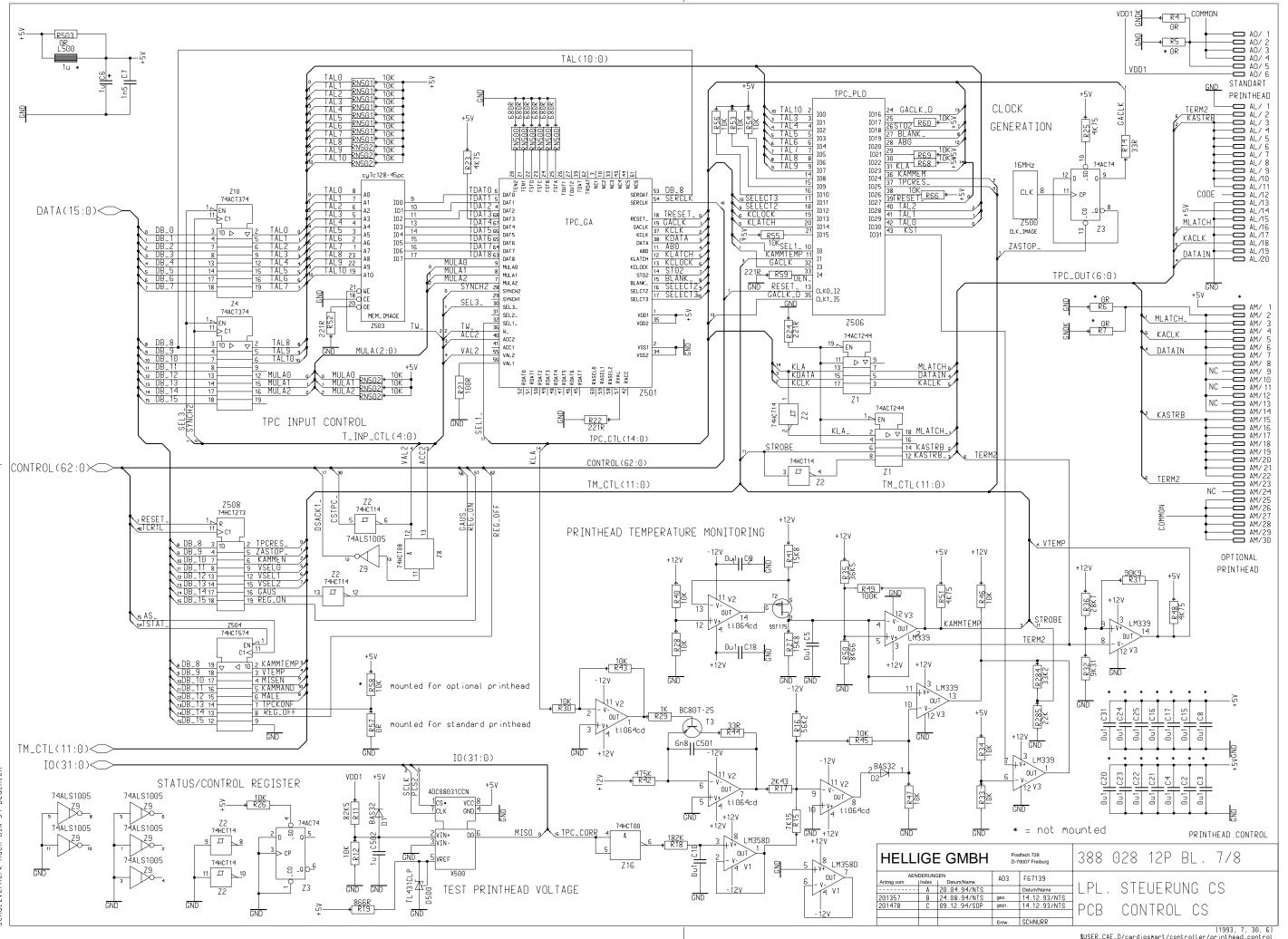
þe 34 DIN



\$USER_CAE_D/cardiosmart/controller

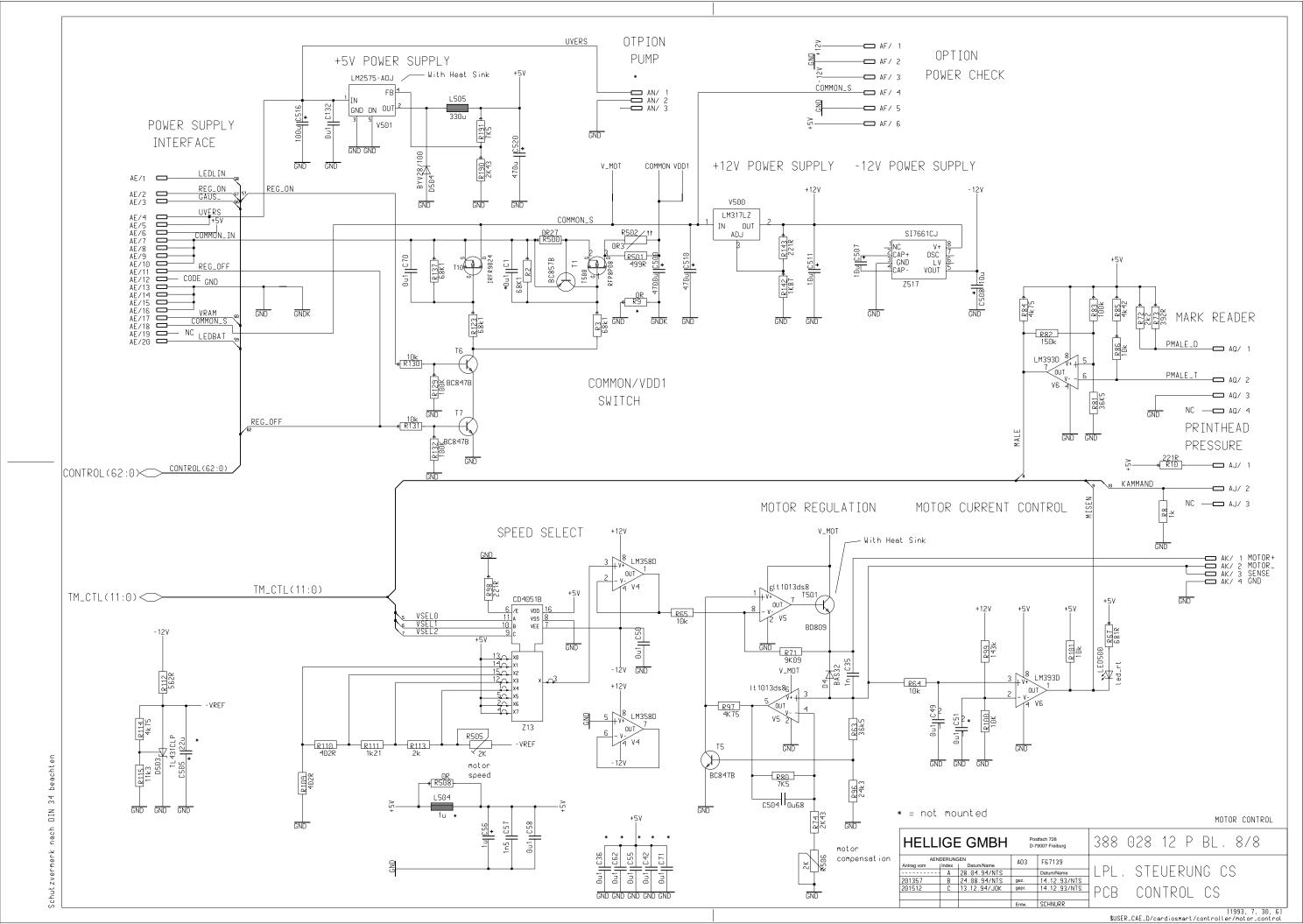


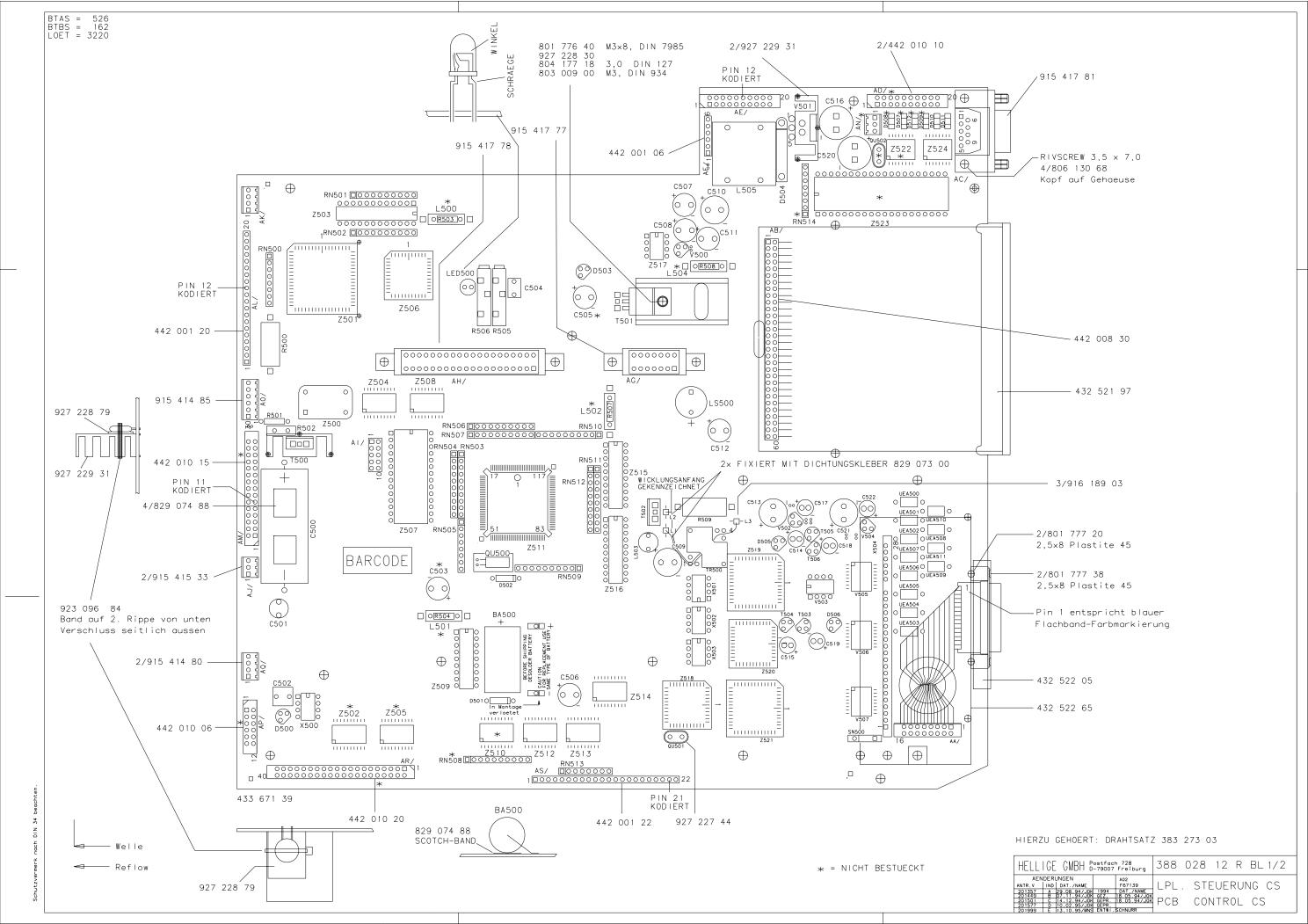
\$USER_CAE_D/cardiosmart/controller/interface_control

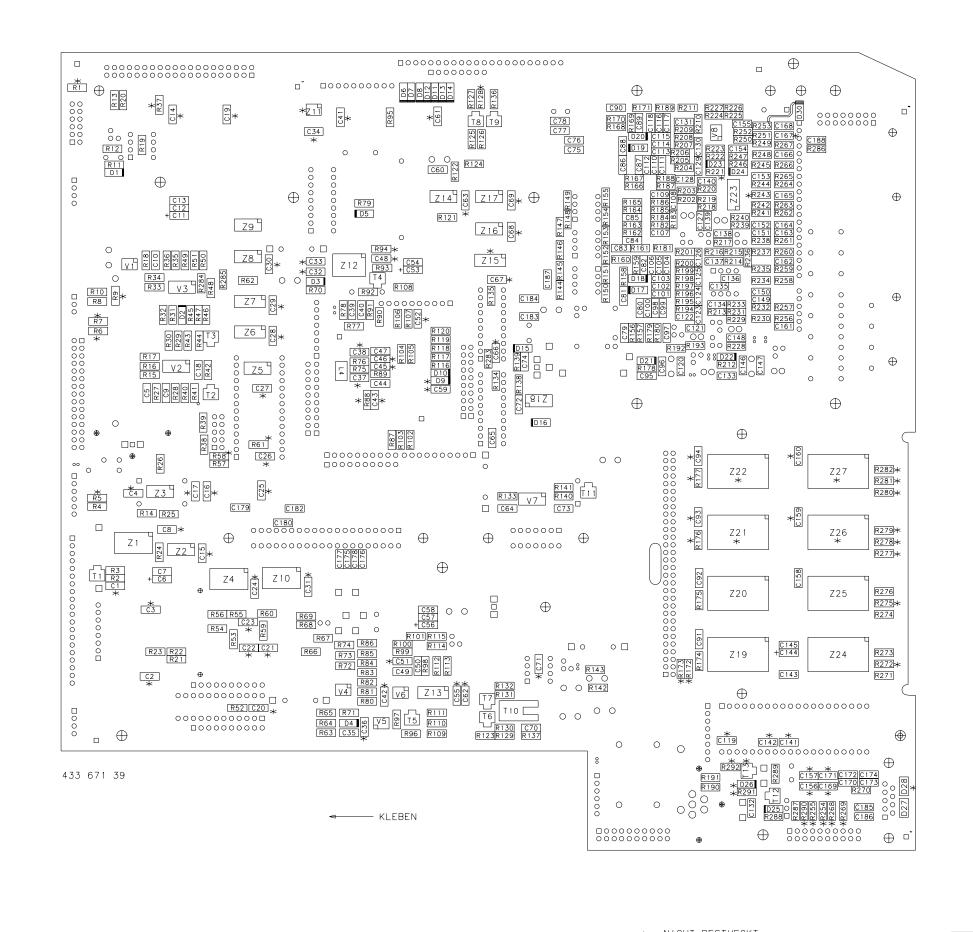


DIN

\$USER_CAE_D/cardiosmart/controller/printhead_control

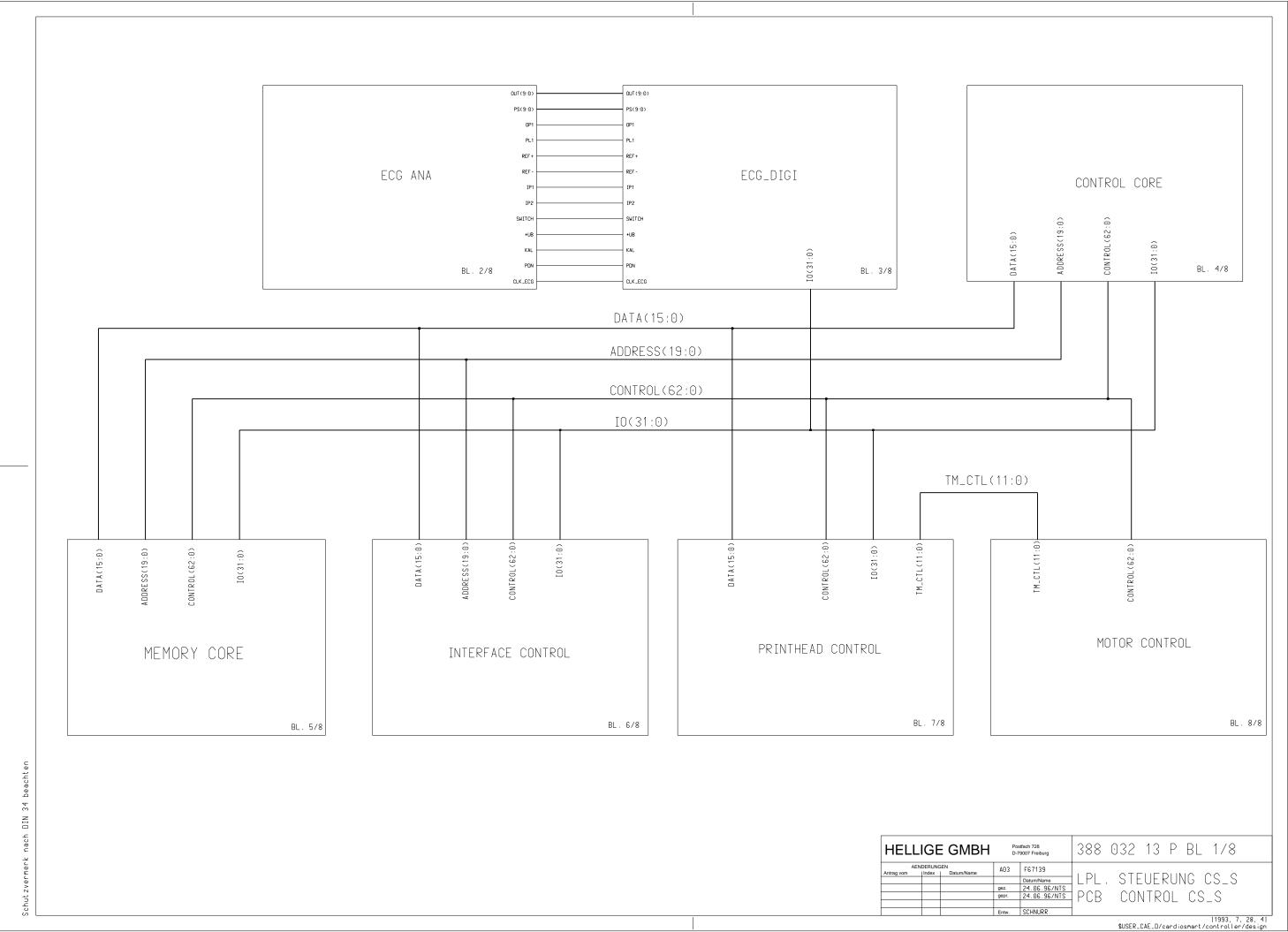




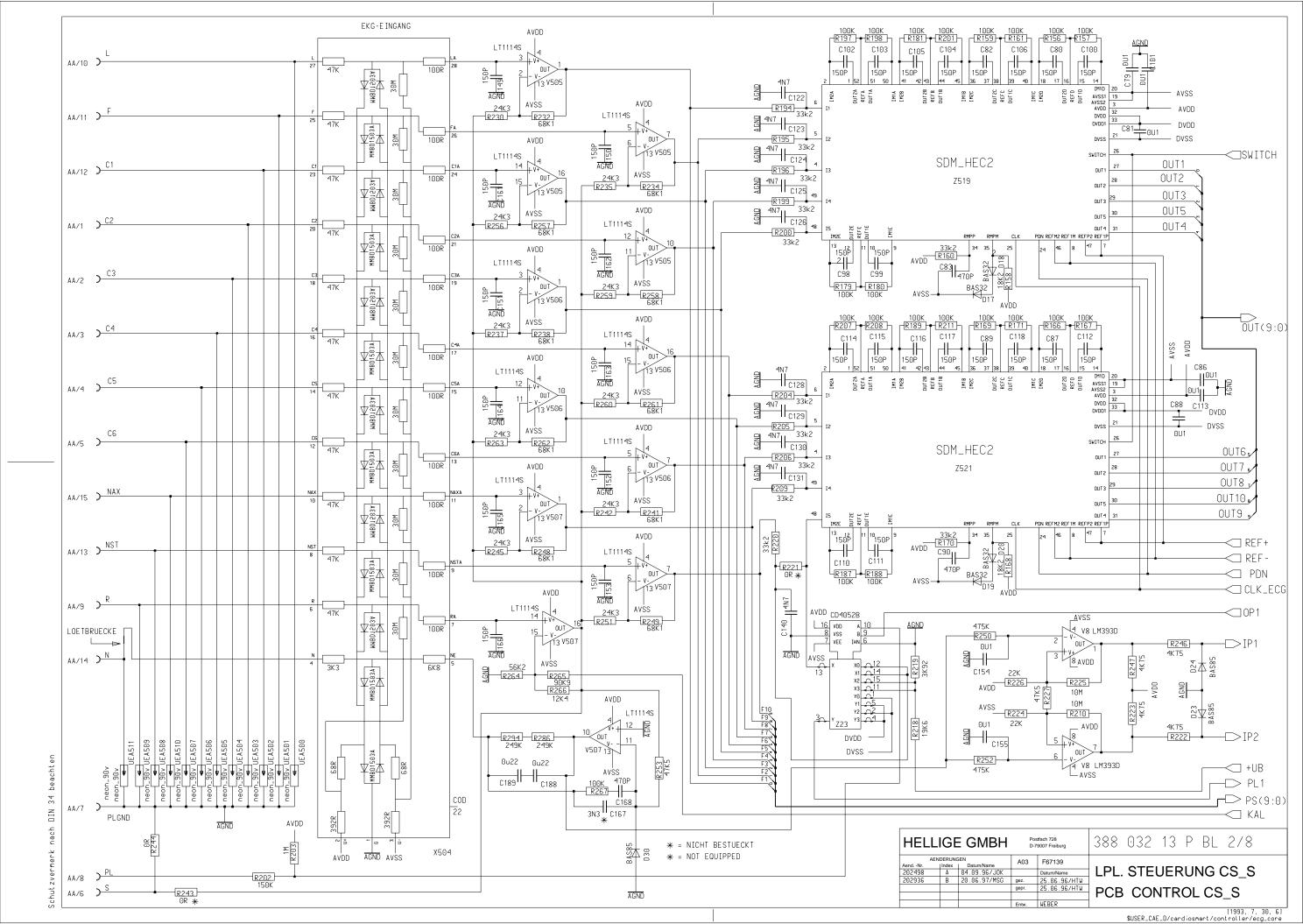


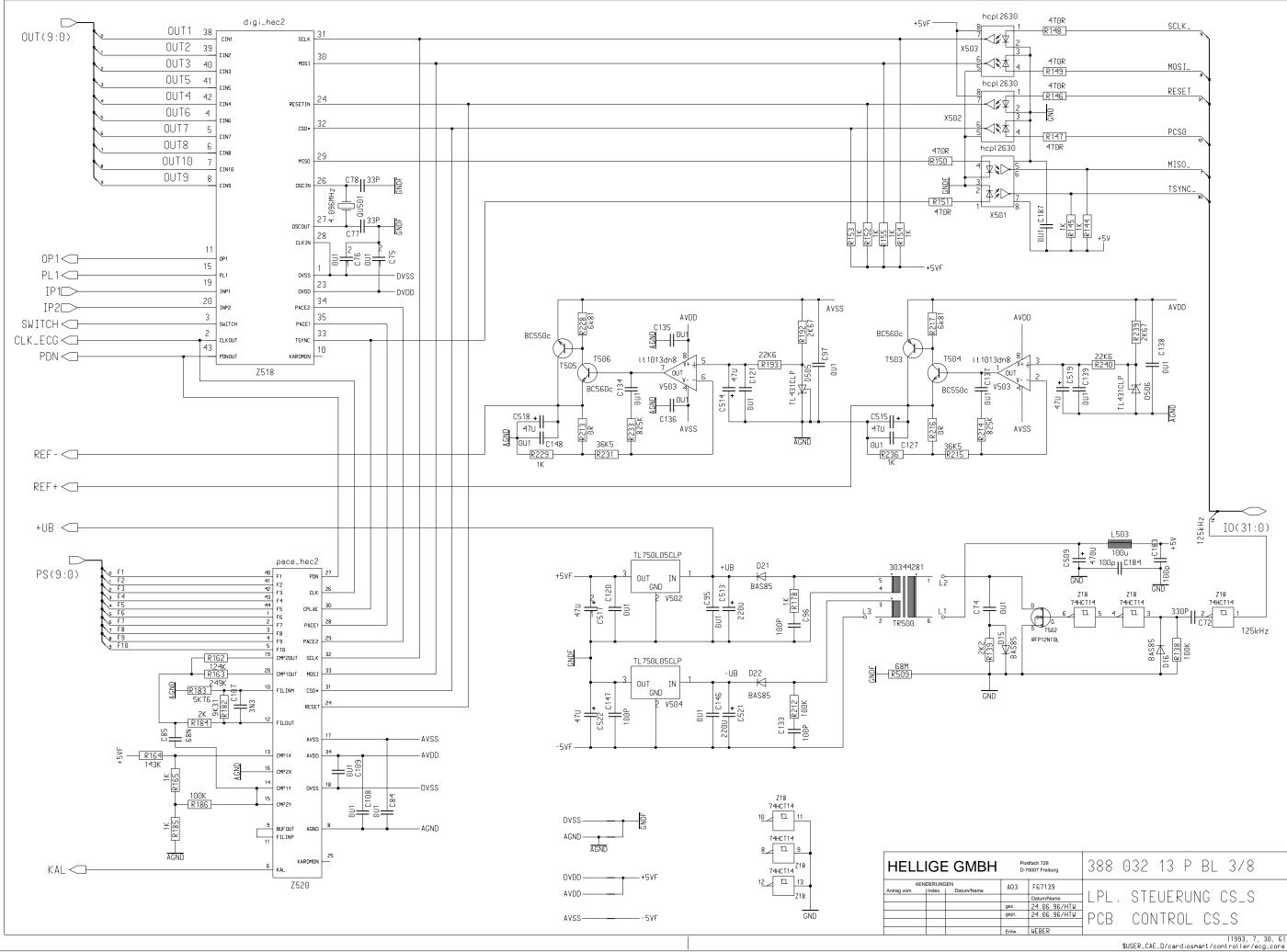
* = NICHT BESTUECKT * = NOT EQUIPPED

HELL	IGE GMBH E	ostfaci -79007	n 728 Freiburg	388	028	12	R	BL2/2
ANTR, V 201810	NDERUNGEN IND DAT./NAME D1 14.05.95/JOK		A02 F67139 DAT./NAME	LPL	. Ste	EUEI	RUI	NG CS
201780 201999 202000 202498	E 15.05.95/JOK F 13 10 95/MNS G 26.10.95/JOK H 04.09.96/JOK	GEPR. GEPR.	18.05.94/J0K 18.05.94/J0K SCHNURR		CON	VTR:	0L	CS

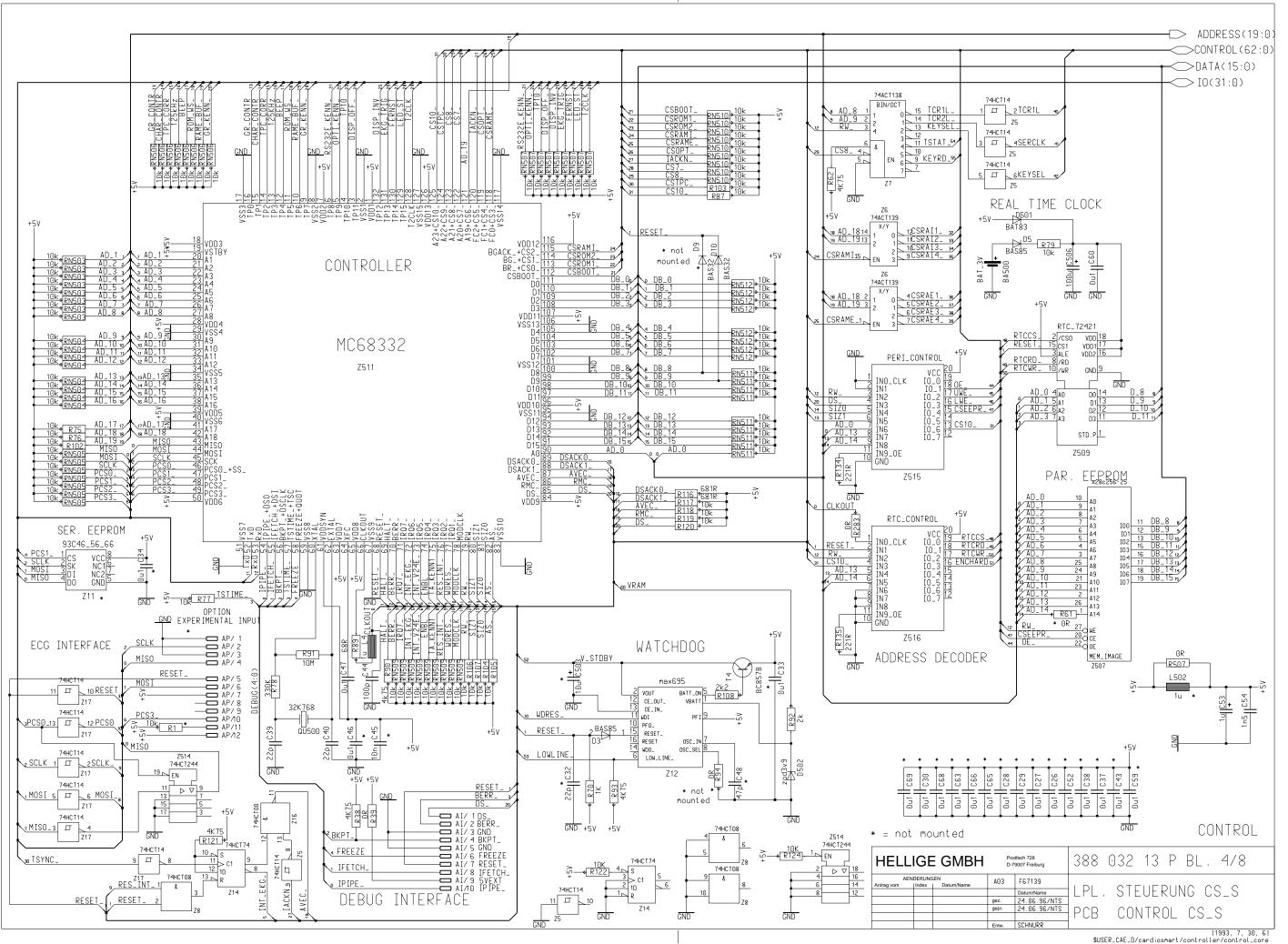


· · · · · ·

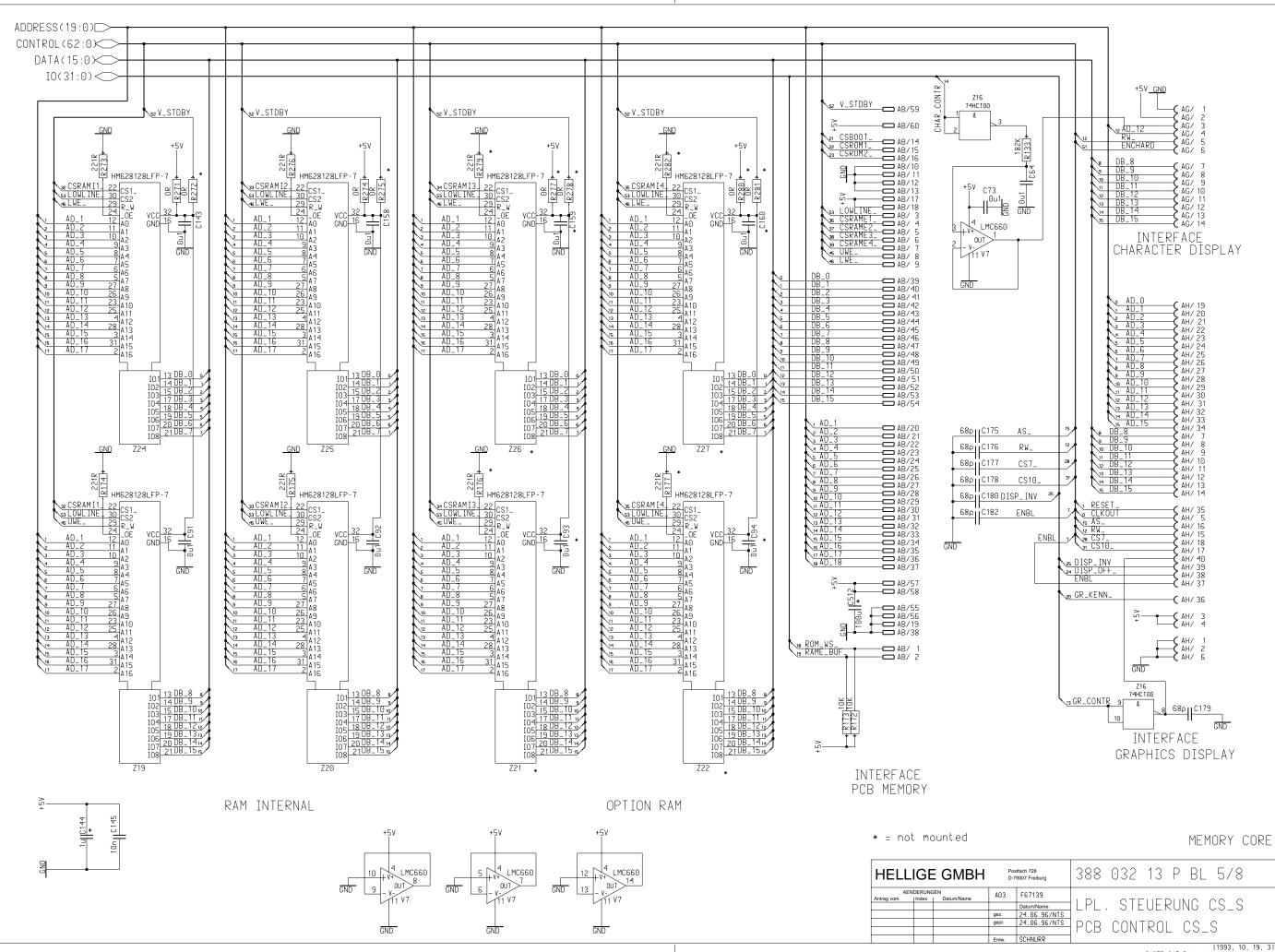




cht 34 DIN nach hut zver

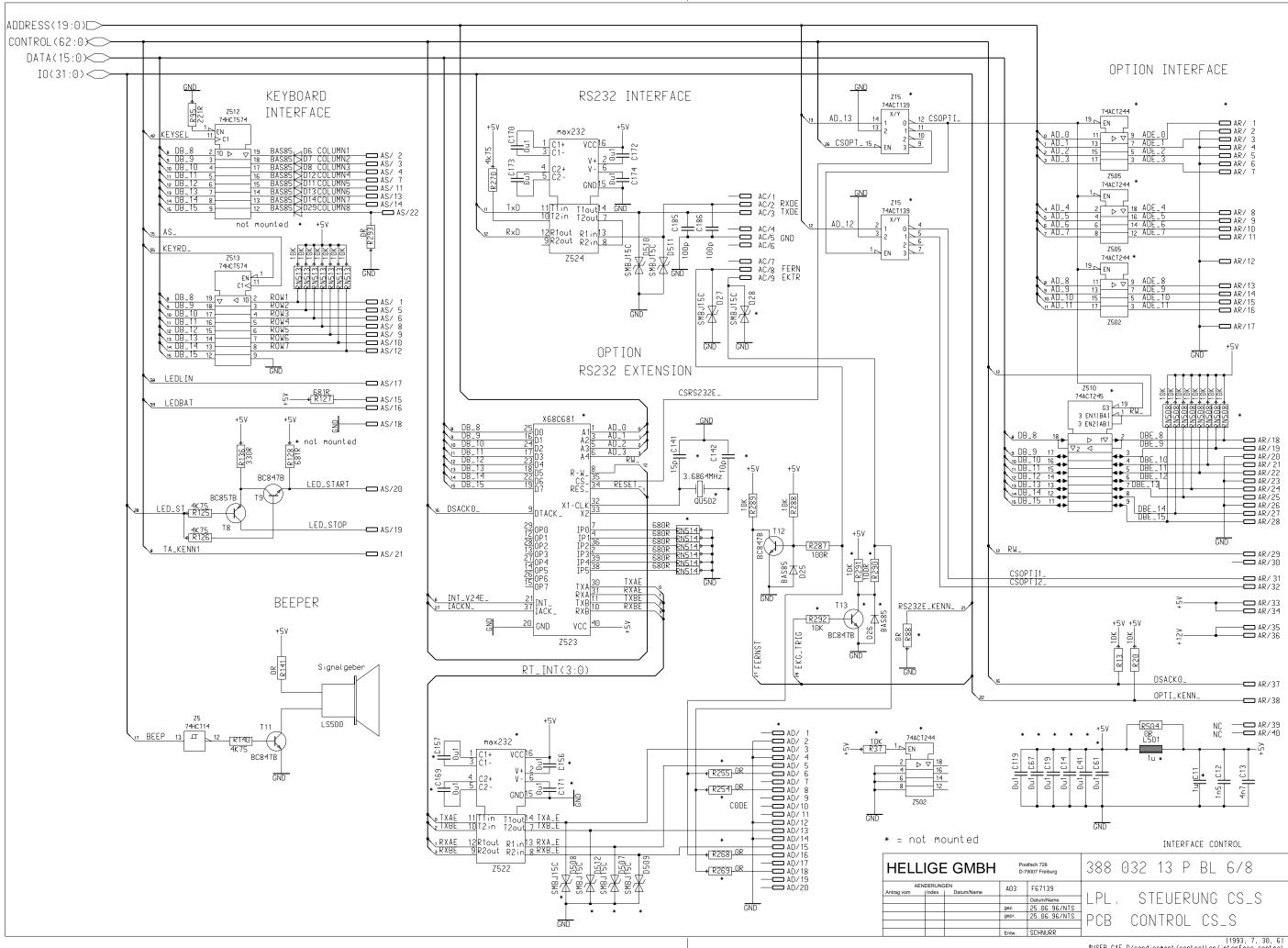


þe 34 DIN

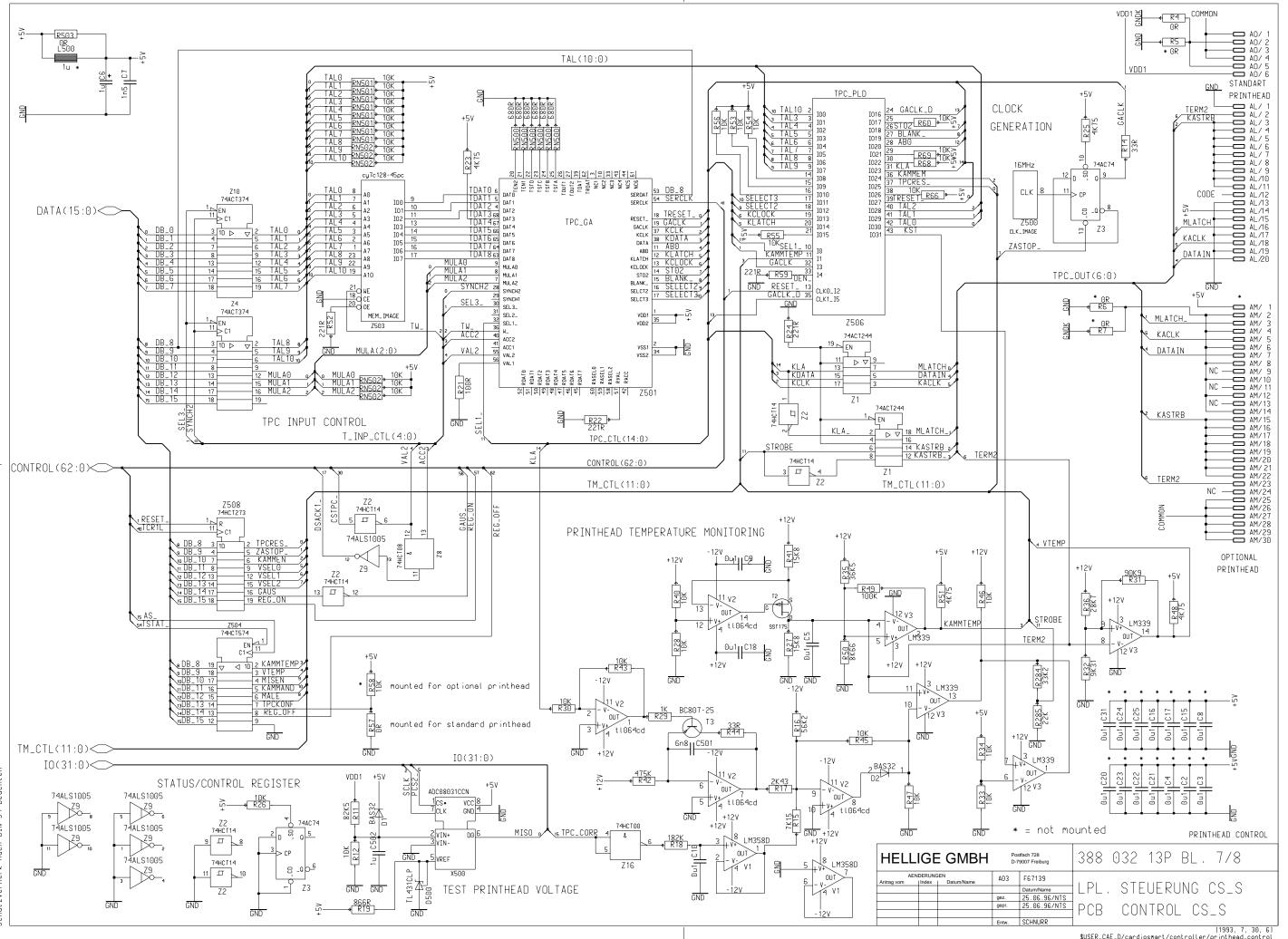


I

\$USER_CAE_D/cardiosmart/controller

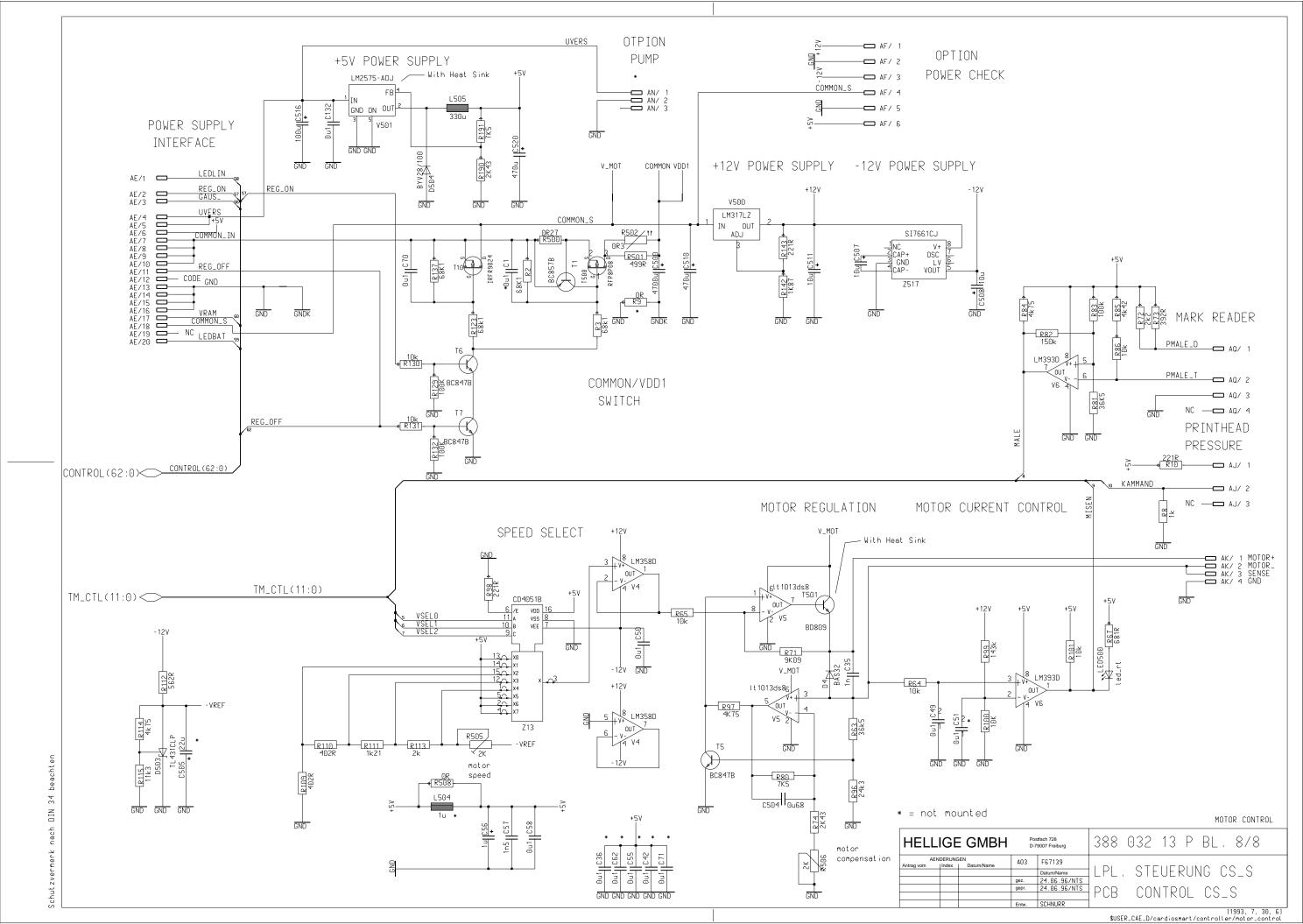


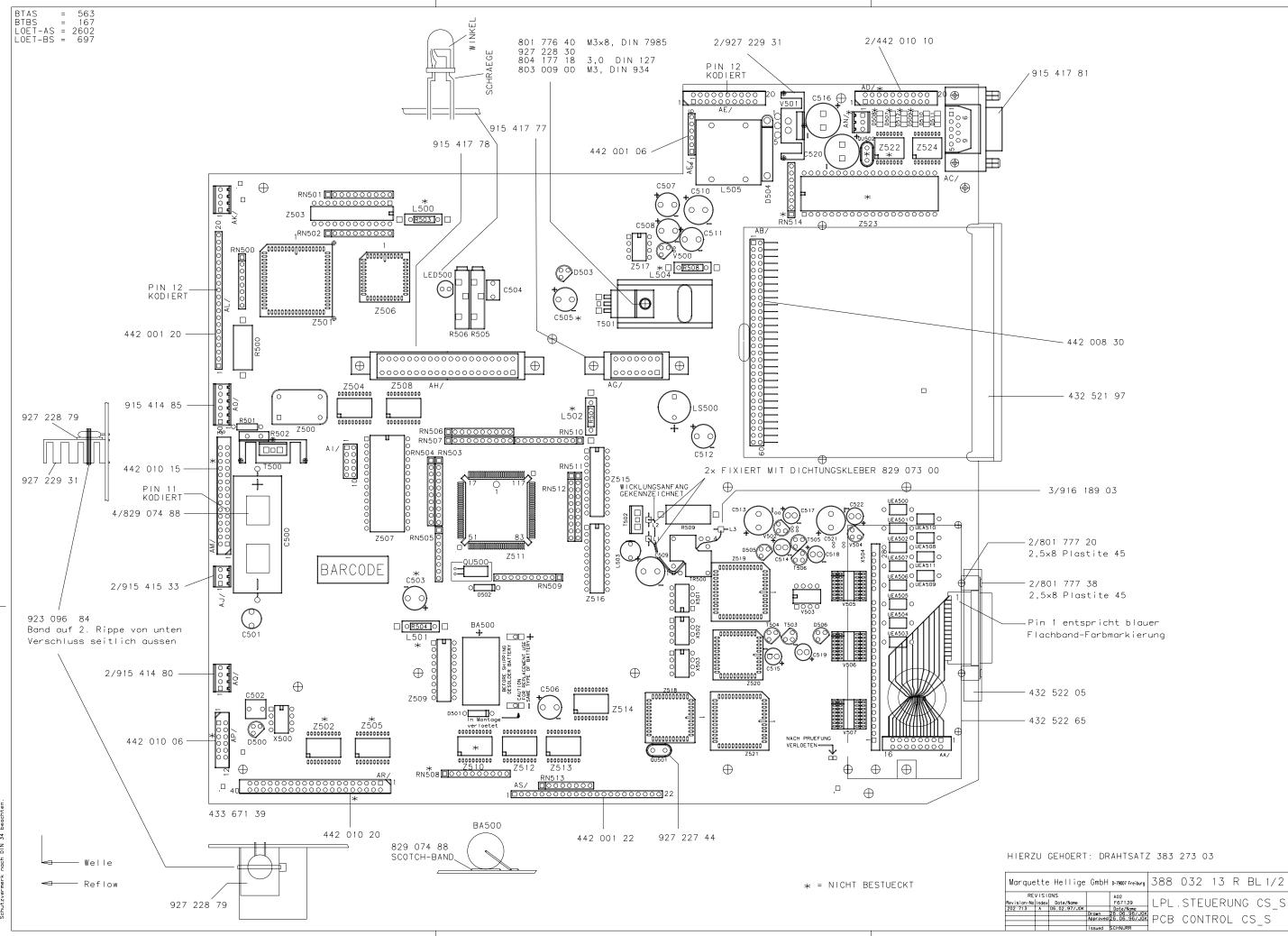
\$USER_CAE_D/cardiosmart/controller/interface_control

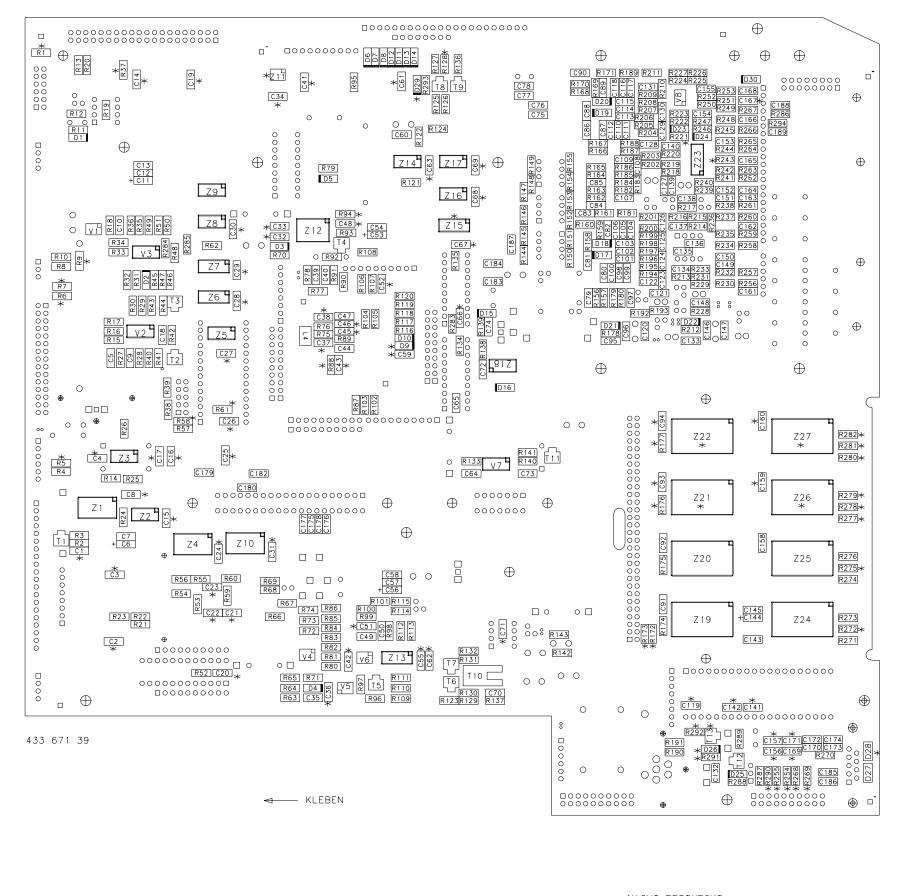


DIN

\$USER_CAE_D/cardiosmart/controller/printhead_control

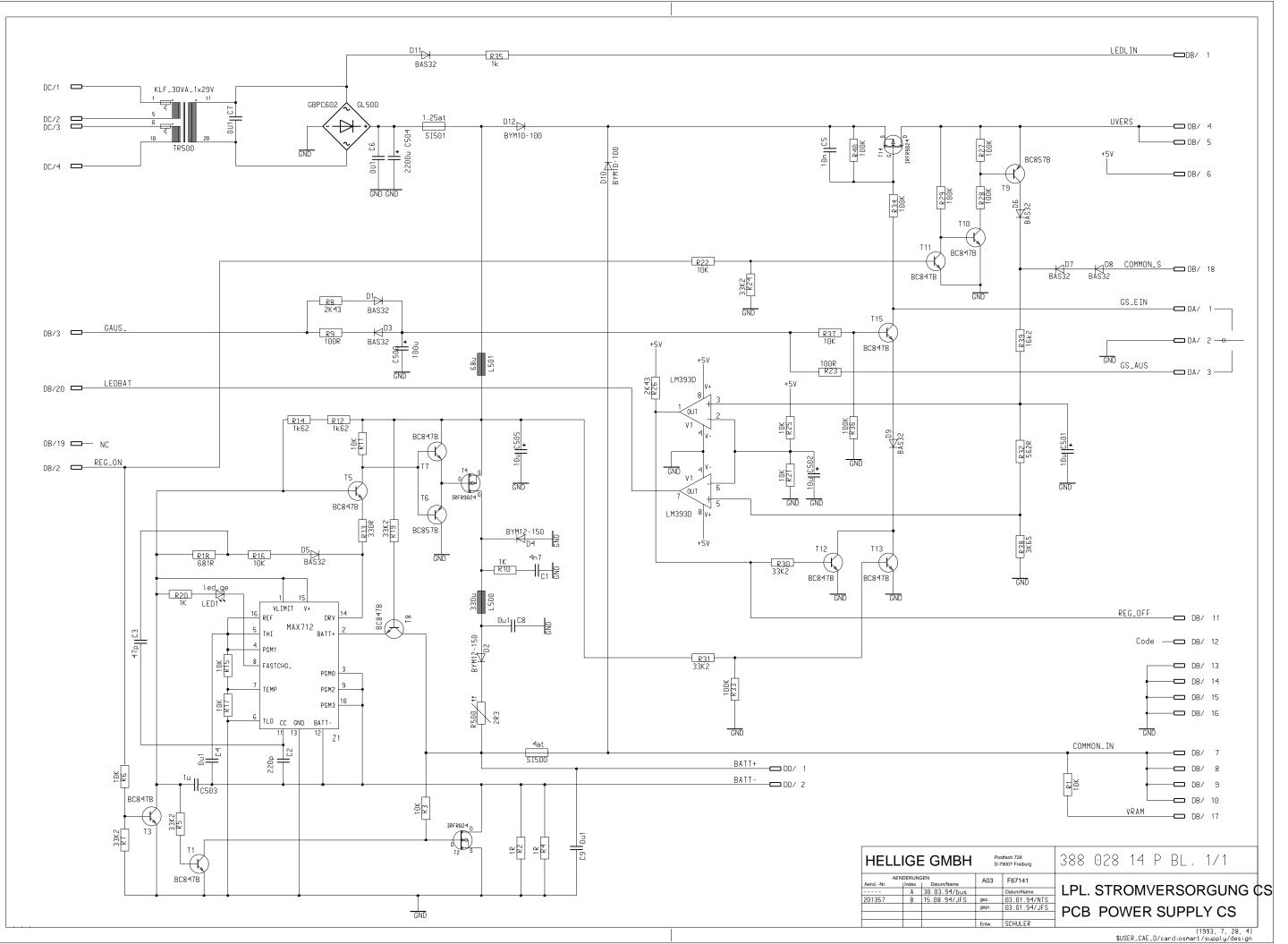


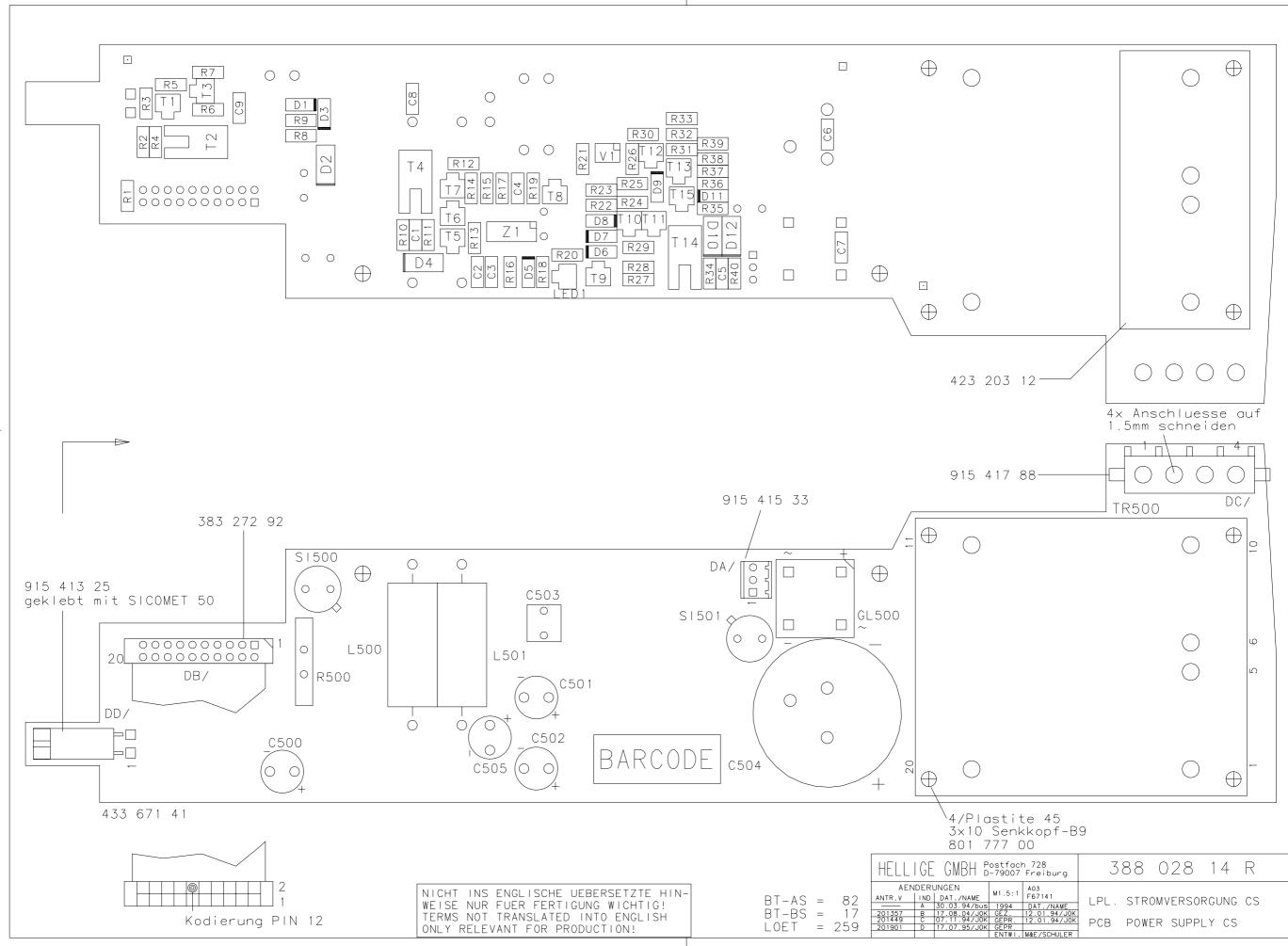




* = NICHT BESTUECKT * = NOT EQUIPPED

Marquett	e Hellige	GmbH	D-79007 Freiburg	388	032	13	R	BL2/2
REVIS Revision-No Inde 202 498 A 202 713 B	Date/Name 04.09.96/JOK	Approved	A02 F67139 Date/Name 25.06.96/J0K 26.06.96/J0K SCHNURR		.STEU CONT			G CS_S CS_S







marquette

A GE Medical Systems Company

World Headquarters GE Marquette Medical Systems 8200 West Tower Avenue Milwaukee, WI 53223 • USA Tel. +1 414 355 5000 800.558.5120 (US only) Fax +1 414 355 3790 Europe Region Marquette Hellige GmbH A GE Medical Systems Company Postfach 60 02 65 D-79032 Freiburg • Germany Tel. +49 761 45 43 - 0 Fax +49 761 45 43 - 233 Asia Region 26/F, Catic Plaza 8 Causeway Road Causeway Bay Hong Kong Tel. +852 2804 2320 Fax +852 2804 1776