EasyOne-CS
Field Service Manual

EasyOne-CS Spirometer

Manufactured for GE Medical Systems Information Technologies

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2030434-006 Rev. D

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1 Manual Purpose

This manual supplies technical information for service representative and technical personnel so they can maintain the equipment to the assembly level. Use it as a guide for maintenance and electrical repairs considered field repairable. Where necessary the manual identifies additional sources of relevant information and or technical assistance.

See the operator manual for the instructions necessary to operate the equipment safely in accordance with its function and intended use.

2 Intended Audience

This manual is intended for the person who uses, maintains, or troubleshoots this equipment.

3 Introduction

The EasyOne-CS Spirometer uses digital ultrasonic flow measurement technology for fast, accurate, reliable operation. The EasyOne-CS was designed for full range testing in primary care, specialty physician, industrial and hospital settings. It offers automated comparison to predicted values, pre- and post Broncho Dilator comparisons, interpretation of results and test quality control that automatically assesses patient effort offering helpful suggestions to obtain optimum results. Optional easy to read and interpret color printout with graphic display for instant test review is available. The single-patient-use spirette minimizes risk of cross-infection.

4 Operation Principle

This EasyOne-CS flow sensor is equipped with two ultrasonic transducers, mounted at different sides of the flow channel. In order to determine gas flow (and molar mass), ultrasonic pulses are transmitted in up- and downstream direction. Precisely measured transit-times are the basis for determining flow and molar mass. The following figure shows a diagram of the flow sensor including its internal sound transmission path.

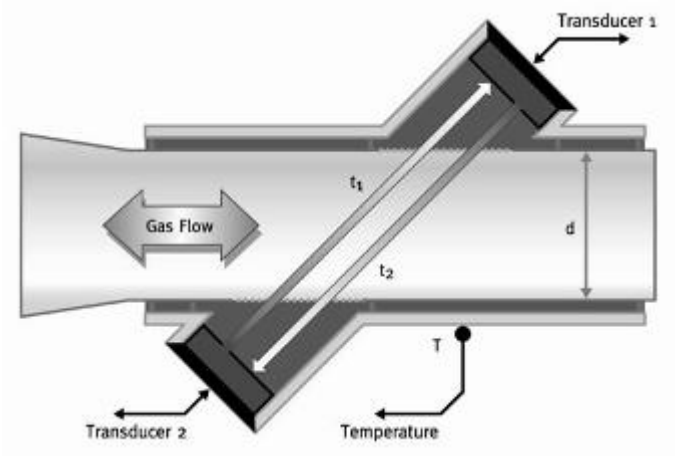


Figure 1: Schematic of EasyOne-CS flow sensor

5 Technical Details

5.1 EasyOne-CS Spirometer Handheld Unit

The following pictures show the top, rear and bottom views of the EasyOne-CS.

Figure 2: Top view of EasyOne-CS

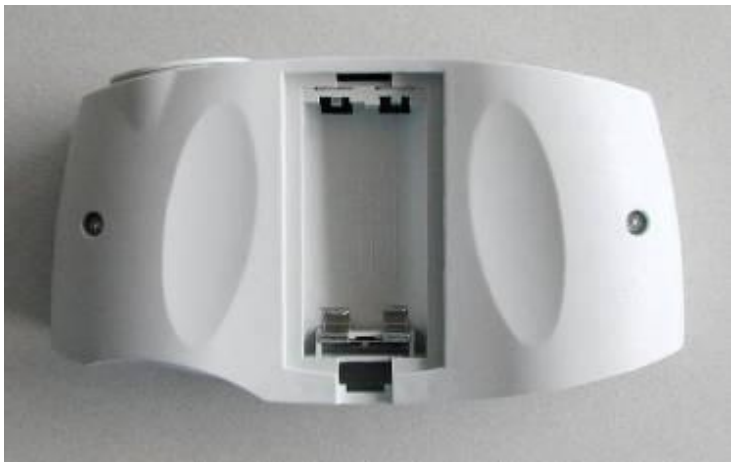


Figure 3: Rear view with empty battery compartment

The two screws on the back side are used to open EasyOne-CS. With the exception of the lithium battery there are no serviceable parts inside the unit. Therefore do not open the unit!

Figure 4: Bottom view of EasyOne-CS

The bottom view shows the name plate, the serial number and the EasyOne-CS-to-Screen-Connector.

5.2 Screen-Connector

The following pictures show the top and bottom views of the EasyOne-CS Screen-Connector.

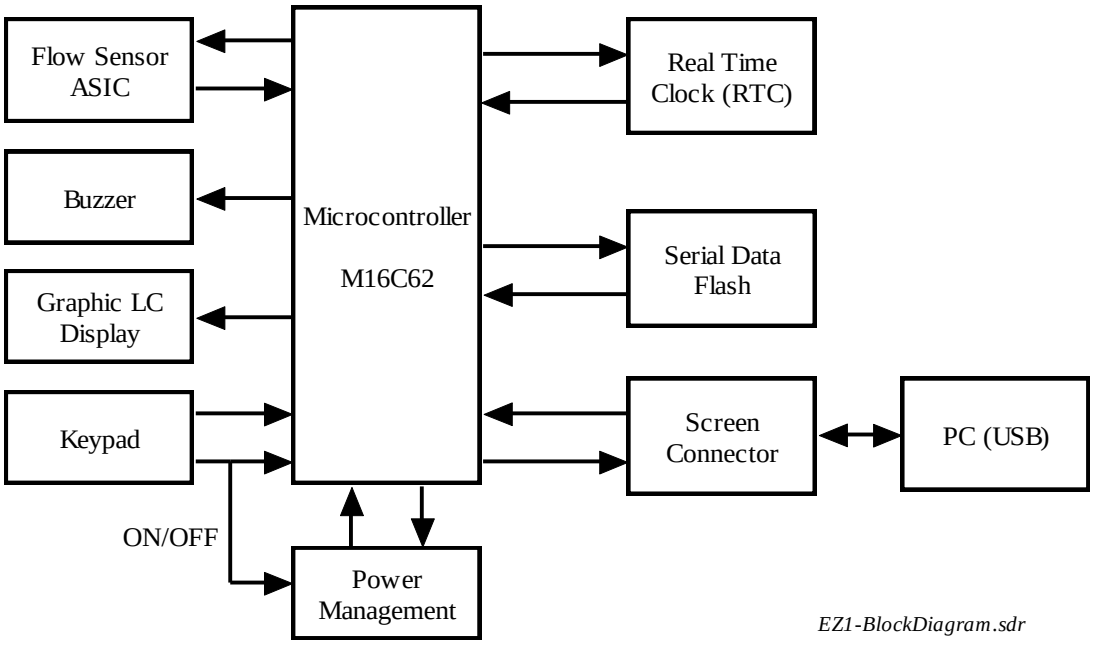
Figure 5: Screen-Connector top view

Figure 6: Screen-Connector bottom view

The Screen-Connector uses a standard USB connection to the PC.

5.3 Block Diagram

The following picture shows the functional block diagram of the EasyOne-CS Spirometer.



5.4 Printed Circuit board

All electrical components of EasyOne-CS are mounted on a single PCB.

With the exception of the lithium battery no components can be serviced.

The following two pictures show a top and bottom view of the PCB.

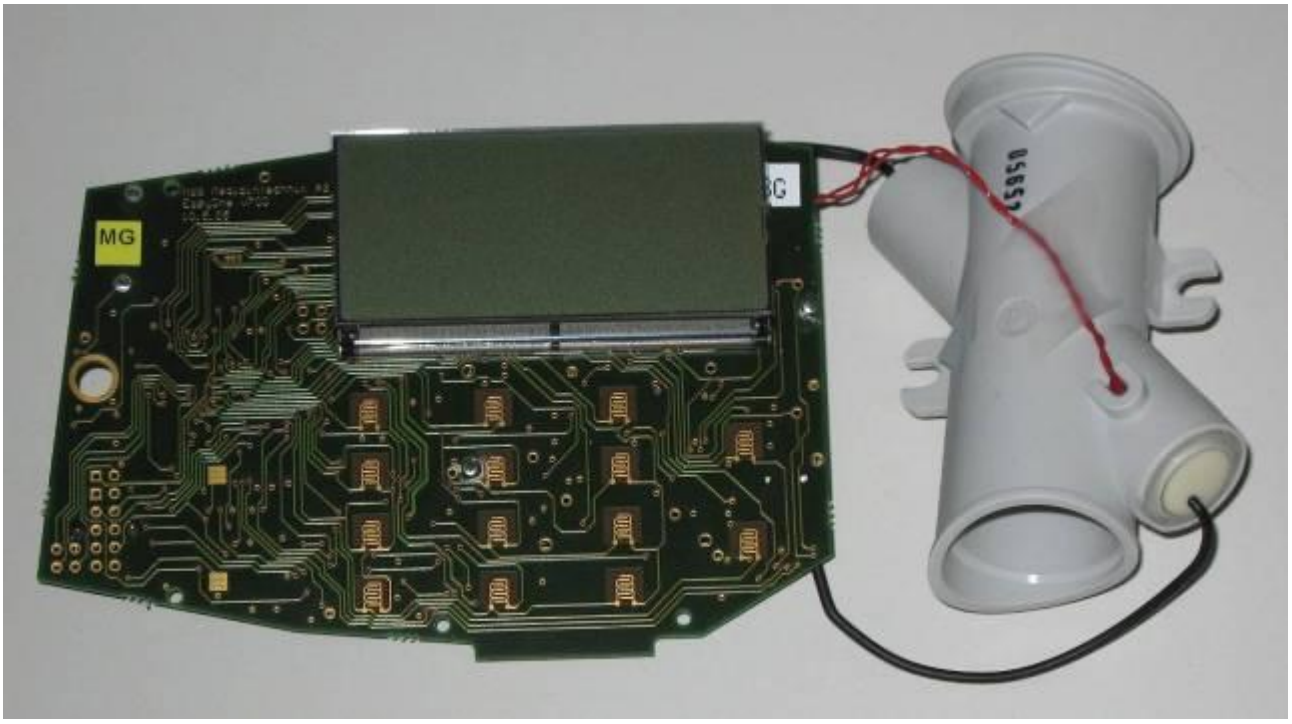


Figure 7: Bottom view of EasyOne-CS PCB

The lithium battery located on the top right of the PCB has an approximate life time of 5 to 10 years. In early revisions of the hardware the lithium battery is soldered on the board.

Figure 8: Top view of EasyOne-CS PCB (without EMI shielding)

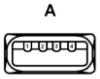
6 Specifications

6.1 EasyOne-CS Model 2001 Spirometer

Size:	83 x 158 x 43 mm (3.3 x 6.2 x 1.7 inches)
Weight:	242 grams (8,6 ounces), with batteries
Measuring accuracy	Volume: ±2% or 0.050 l Flow: ±2% or 0.020 l/s, (except PEF) PEF: ±5% or 0.200 l/s MVV: ±5% or 5 l/min.
Measuring range:	Volume: ±12 l Flow: ±16 l/s
Resistance:	below 0.3 cm H_2O/L/s
Display:	64 x 160 graphic display
Data entry:	14-key keyboard
Data memory:	For up to 700 tests, stored in EasyOne CS
Test modes:	FVC, FVL, Slow VC, MVV, Pre/Post
Parameters:	FVC, MVV, FEV6, FEV1, FEV1/FVC, FEV1/VC , FEV1/FEV6, MEF25 (FEF75), MEF50 (FEF50), MEF75 (FEF25), MEF25%-75%, PEF, FET, FIVC, PIF, IVC, ERV, IRV, pre-post % variation, Lung Age
Respiratory tube:	Disposable spirette respiratory tube
Measurement principle:	Ultrasound transit-time measurement
Adult predicted:	NHANES-III, Knudson_83, Knudson_76, Crapo, Morris, ERS (ECCS/EGKS), Forche (Austria), Sapaldia (Switzerland), Roca (Spain), Berglund, Gulsvik, Hedenström, Gore, Cherniak (only for MVV)
Pediatric predicted:	Dockery (Harvard), Hsu, Zapletal, Polgar, Hibbert
Power supply	2 alkaline batteries, Type AA, 1.5V
Power consumption:	Typical 0.6 W
Report:	A4
Storage:	Temperature: -20 to 50 °C Relative humidity: 5% to95% Ambient pressure: 500 to 1060 hPa

Operating conditions:	Temperature: 0 to 40 °C Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
Certifications and standards:	CE Declaration of Conformity C CSA US approval, CAN/CSA-C22.2 No. 601.1-M90, S1-94, CSA 601.1 Amendment 2:1998, UL Std No. 2601.1 FDA 510 (k) approval, K993921 EasyOne-CS meets or exceeds the published targets of the European Respiratory Society (ERS), the American Thoracic Society (ATS) and the National Lung Health Education Program (NLHEP).
Instrument classification:	Type BF applied part (when used with a PC, protection class 2 according to IEC 60601-1) Instrument not suitable for use in flammable anesthetic gases in mixtures with O_2 or NO.
Life time:	7 years

6.2 EasyOne-CS Model 2010 Screen-Connector

Size:	64 x 44 x 25 mm (2.5 x 1.7 x 1.0 inches)
Weight:	82 grams (3 ounces)
Power supply:	From USB port
Power consumption:	Type 0.15W
Function:	Connects the EasyOne-CS spirometer to a PC
Interface:	Standard USB type A connector for connection to PC  Pins: 1 = VBus, 2 = D–, 3 = D+, 4 = GND
Storage:	Temperature: -20 to 50 °C Relative humidity: 5% to 95% Ambient pressure: 500 to 1060 hPa
Operating conditions:	Temperature: 0 to 40 °C Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
PC:	The PC must comply with corresponding IEC standard (ex. IEC 60950-1. The user is responsible that requirements of IEC 60601-1-1 for safety of medical electrical systems are met.

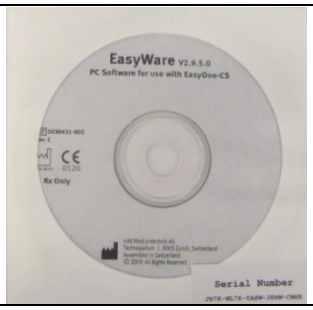
7 Replacement Parts List

The following parts are available for replacement:

7.1 Manuals

Part Number Short Description	Description
2030434-006 MNL SVCE EASYONE-CS	Field Service Manual (this document)
2030434-013	Operator's Manual German
2030434-014	Operator's Manual English
2030434-015	Operator's Manual French
2030434-016	Operator's Manual Italian
2030434-017	Operator's Manual Spanish
2030434-018	Operator's Manual Portuguese
2030434-019	Operator's Manual Danish
2030434-020	Operator's Manual Dutch
2030434-021	Operator's Manual Chinese
2030434-023	Operator's Manual English-US

7.2 Accessories

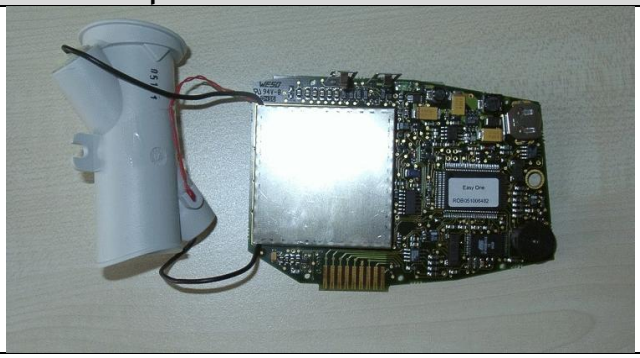
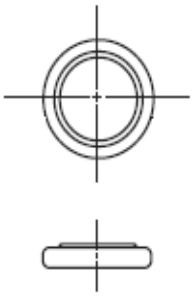
Part Number Short Description	Description
2030431-003 CABLE EASYONE-CS - PC 	Screen-Connector, connects EasyOne-CS with the PC via USB connection
2030431-005 CD EASYWARE V2.9.5 	CD with EasyWare V2.9.5 software
2030431-006 SPLY SPIRETTES #50 	50 spirettes
2030431-007 SPLY SPIRETTES #200 	200 spirettes
2030431-008 SPLY NOSECLIP #25	25 nose clips

2030431-009 SPLY PAD FOR NOSECLIP #100	100 pads for noseclips
2030431-010 SPLY CALIBRATION SYRINGE EASYONE-CS	Calibration syringe

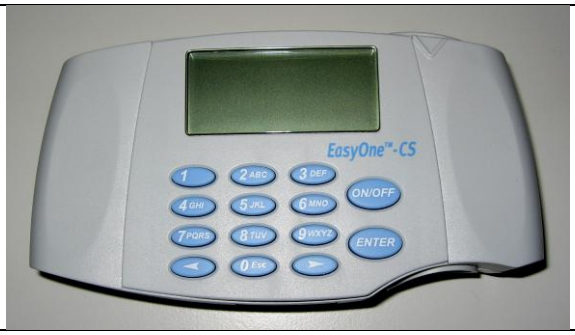
7.3 Spare Parts

Part Number Short Description	Description
2033231-001 SPARE EASYONE-CS FRONTHALF	Case front half

Part Number **Short Description**	**Description**
2033231-002 SPARE EASYONE-CS REARHALF	Case rear half
2033231-003 SPARE EASYONE-CS BATTERY DOOR	Battery door
2033231-004 SPARE EASYONE-CS KEYPAD	Keypad
2033231-005 SPARE EASYONE-CS SCREW SET	Screw set, consisting of: - #1 Spring lock ring 12mm - #2 Torx screw K30x6, WN1452 - #2 Washer - #2 Allen screw M3x25 - #2 Hook-sleeve 5.6x6.5
2033231-006 SPARE EASYONE-CS BOARD WITH SENSOR	- PCB board with sensor and programmed serial number

Part Number Short Description	Description
	- Serial number label (Silver label)
2033231-007 SPARE EASYONE-CS LITHIUM BATTERY 	BR1225 Lithium battery coin

7.4 Exchange Unit

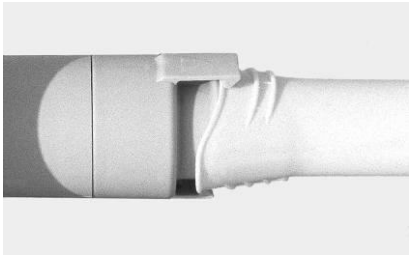
Part Number Short Description	Description
2030431-002 RCDR EASYONE-CS 	EasyOne-CS unit for exchange

8 Checkout Procedure

After repair or maintenance of the EasyOne-CS the following procedure is recommended in order to check correct operations of EasyOne-CS:

- Optional step: If all data in EasyOne-CS must be deleted, perform the 'hidden key' sequence 1-2-5 described in the following chapter in order to perform a factory reset. Please be aware that this step clears all customer data and resets the device to factory default settings.
- Get a calibration adapter and a calibration syringe (2030431-010)
- Ensure that the correct syringe volume is entered in the instrument's configuration setting.
- Choose item "Check calibration" in the main menu of EasyOne.

- Connect the spirometer as shown below using the calibration adapter and the syringe. Ensure that the piston is fully inserted and at the stop position.



- Now press ENTER.
- Wait until the baseline has been set and you hear an audible signal.
- Now execute one full inspiratory pump stroke followed by one full expiratory pump stroke at moderate speed.
- After you perform the maneuver, you will see the text "Accuracy confirmed" at the top of the display and, beneath it, the percentage deviation and the average flow velocity of the pump stroke.
- If desired, make a printout of the calibration report.

9 Hidden Keys

The “hidden key” sequences access special features that are not available in the standard menu structure of EasyOne-CS. The following table shows what key sequences are available. The column labeled ‘Location’ indicates in what menu / screen the described key sequence has to be used.

Caution: The key sequences should not be used in conjunction with patient testing.

Location	Key sequence	Description
Main Menu	1-3-5	Factory defaults (same as in Configuration Menu).
Device self test error screen	1-3-5	Ignore error and go on. Use only for troubleshooting! Do not perform a patient test, because the results could be errorneous
Device info screen (from Configuration Menu).	1-2-4	Show additional device information.
Device info screen	1-2-5	Hard factory reset (configuration settings are reset and database is deleted (In case of synchronisation with EasyWare, please do not forget to synchronize EasyOne with new database.)
Device info screen	1-2-6	FVC filter disable temporarily (until next power cycle).
Device info screen	1-2-7	Switch off BTPS correction temporarily (until next power cycle).
Device info screen	1-2-8	Switch off flow linearity correction temporarily (until next power cycle).
Device info screen	1-3-9	Restore corrupt database: Caution use only for inconsistent databases

10 Device Error Codes

Internal errors are reported using the following screen:

ERROR
Device Selftest
Failure #xx
Please contact
service

The number xx indicates the type of error that is detected. The following list shows all error numbers and a description of the internal error.

No.	Description
1	internal software error (wrong argument)
2	internal software error (unsupported)
3	internal software error (timeout)
4	internal software error (data inconsistent)
5	internal software error (write error)
6	internal software error (read error)
7	internal software error (not found error)
13	internal software error (WD timeout)
14	the ultrasonic receive amplitude is too low (check spirette insertion)
15	the ultrasonic receive amplitude is too high (check spirette insertion)
16	Bootloader software inconsistent (CRC failure)
17	User software inconsistent (CRC failure). Update EasyOne-CS device software.
18	Calibration data inconsistent.
19	Failure of flash memory.
20	Flow sensor transit time range check error. Possible reasons: a) Blocked sound path, e.g. caused by wrongly inserted spirette, b) almost empty batteries.
21	ndd ASIC serial transmission error (STX expected)
22	ndd ASIC serial transmission error (sequence error)
23	ndd ASIC serial transmission error (unknown character)
24	Real time clock RAM error
25	Configuration data inconsistent (lithium battery failure possible)
49	internal software error (overrun error)
50	internal software error (timeout error)
51	internal software error (storage error)
52	internal software error (record structure error)
53	internal software error (address error)
54	Serial data flash or serial communication data inconsistent (CRC failure)
55	internal software error. Writing to the internal Flash failed (flash command sequence error)
56	internal software error. Erasing the internal Flash failed (flash block erase error)
57	internal software error. Writing to the internal Flash failed (flash program error)
65	internal software error. Writing to the internal Flash failed (flash block program error)
66	internal software error. Accessing the internal Flash failed (flash busy)
67	First record of database reached. Go beyond this record failed (FIRST_RECORD)
68	Last record of database reached. Go beyond this record failed (LAST_RECORD)
69	No valid record in the database found (NO_VALID_RECORD)
70	internal software error (UNKNOWN_ERROR)
144	Sensor serial communication error

11 EasyOne-CS Device Software Update

11.1 Introduction

The internal software of EasyOne-CS is stored in a Flash EPROM. It is therefore possible to update the internal software. The following procedure describes how this update is executed.

11.2 Validated Upgrade Steps

The following upgrade steps are validated:

Old Version	New Version	Item Number	EasyOne-CS device software	CRC
V04.01.00.00	V04.03.00.00	2033231-008	GE-EOV04030000-P-EU_Resources.hex with EU language package	0xF3D7

11.3 Preparation

The following items are required:

- 2033231-008.zip (upgrade package with EasyFlash and EasyOne-CS device software V4.3)
- ndd Screen-Connector cable 2030431-003.
- PC program EasyFlash, V2.4.12 or higher.
- EasyOne-CS device software for the download (*.hex).
- PC with Windows 2000, XP or Vista (all 32 Bit).

The following installation description presumes that you have basic knowledge of your PC operating system.

11.4 Unpacking of Upgrade Package

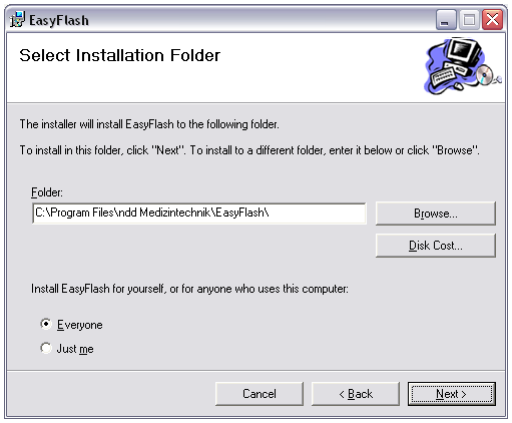
After getting upgrade package 2033231-008.zip the zip archive can be extracted to a folder of your choice, e.g. to C:\nddmed\2033231-008.

11.5 Installation of EasyFlash PC Software

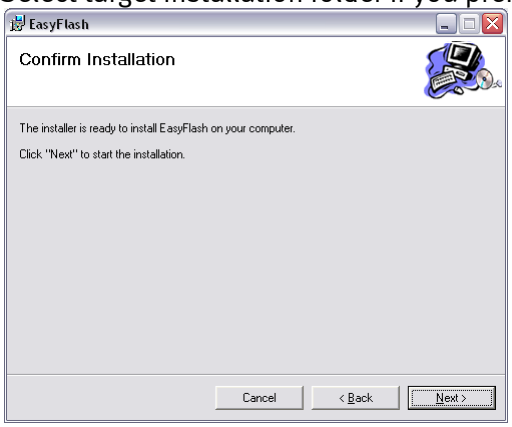
The PC software EasyFlash is needed to update EasyOne-CS device software:

1. Start “C:\nddmed\2033231-008\EasyFlash\Setup.exe” to install the EasyFlash software.

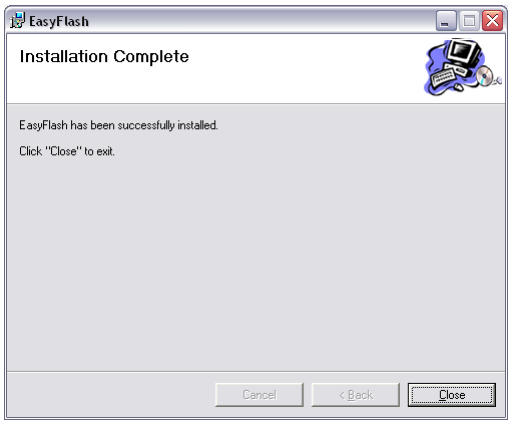
2. Click “Next ›”



3. Select target installation folder if you prefer another one. Click “Next ›”.



4. Click “Next ›”

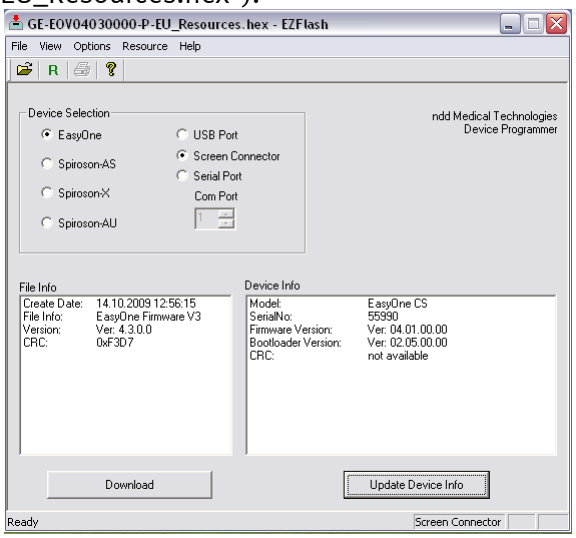


5. The EasyFlash software is now installed on your PC. Click “Close” to terminate the setup program.
6. To start EasyFlash you find an appropriate short cut in the start menu of your PC.

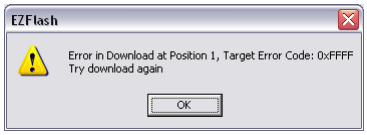
11.6 EasyOne-CS Device Software Update Procedure

In order to update the EasyOne-CS device software follow this procedure:

1. Connect the EasyOne-CS Screen-Connector with an unused USB port of your PC.
2. Turn the power of EasyOne-CS on and connect it with the ScreenConnector. The EasyOne-CS display shows: „EasyOne“.
3. Start the PC software “EasyFlash”.
4. Set “Device Selection” to “EasyOne” and communication port to “Screen Connector”.
5. Press the “Update Device Info” button. The window on the right side shows the Model and the version information of the EasyOne-CS.
6. The device software can be selected through selecting the “Open” icon or with menu command “File/Open” C:\nddmed\2033231-008\ EasyOne-CS V4.3 Firmware EU\GE-EOV04030000-P-EU_Resources.hex”).



7. The programming is started by pressing the “Download” button. You are requested to enter your company and user name.
8. Under certain circumstances the following message can appear.



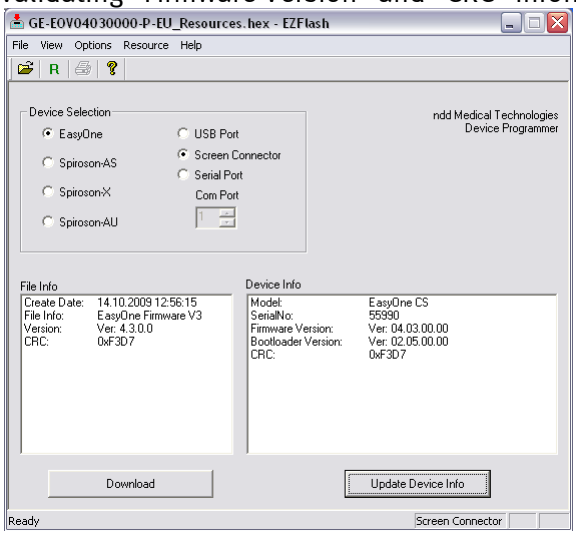
In order to procede perform the following steps.

   a. Click “OK”.
   b. Disconnect EasyOne-CS from the ScreenConnector. The display of EasyOne-CS shows “Receive Idle mode, Setting 19200 Baud”.
   c. Reconnect EasyOne-CS with the ScreenConnector
   d. Click “Update Device Info” and press the “Download” button again.

9. During the programming of EasyOne-CS a progress bar is shown. The programming takes approx. 3 to 5 minutes. Please do not interrupt the programming process. After successful programming the following message is shown:

10. The EasyOne-CS device has to be restarted using the ON/OFF key.

11. The correct programming can be checked by pressing “Update Device Info” button and validating “Firmware Version” and “CRC” information.



Troubleshooting:

- If the programming of the software is interrupted: Turn the power of EasyOne-CS off and turn it on again. Retry the programming procedure.

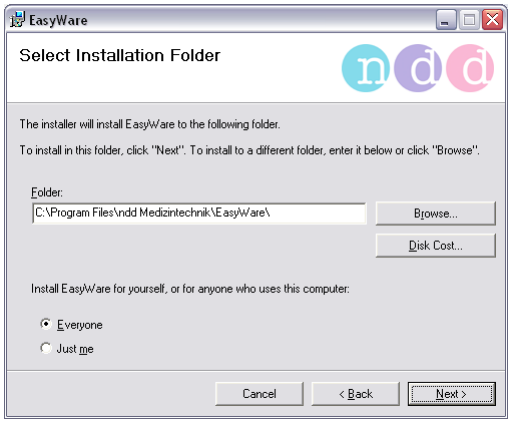
12 EasyWare PC Software Installation

You will require Administrator privileges to install the software. Proceed as follows:

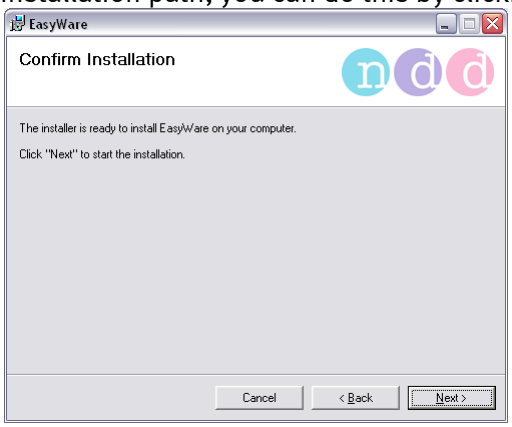
- **Do not yet** connect the ScreenConnector to the PC.
- You will require Administrator privileges on the PC in order to install the software.
- Quit all programs and insert the EasyWare CD into your CD ROM drive. The installation routine should start automatically within 30 seconds of inserting the CD. If the installation routine does not start automatically, switch to root directory on the CD-ROM and run the "SmartInstallation.exe" program. You will then see the following window:

- Click on "Install EasyWare".

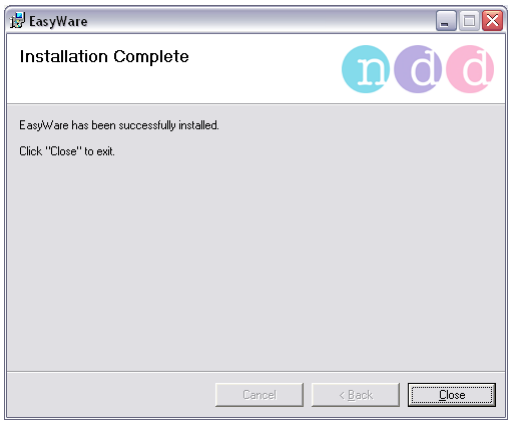
- Click on "Next ›".



- In the bottom part of the window, you can still select whether this application is to be installed for all users ("Everyone") or for you only ("Just me").
- Click on "Next ›" to confirm the displayed installation path. If you wish to change the displayed installation path, you can do this by clicking on "Browse..."



- Confirm the summarized installation information by clicking on "Next ›".



- If button "Install FlashPlayer" is not visible the Macromedia FlashPlayer has also been installed automatically. Confirm completion of installation by clicking on "Close".

- Optional: On Windows Vista the FlashPlayer has to be installed manually (Macromedia Flash Player must be installed on your system in order to display the pediatric animation). Click on "Install FlashPlayer" if button is displayed.
-

- Confirm installation by clicking on “Yes”.
-

- Click on "OK".

- Your computer may need to be restarted during this installation procedure under certain circumstances.
- The SmartInstaller can be terminated by clicking on "Exit". Remove the CD from the drive.
- An EasyWare icon will have been installed on your desktop after installation.
- Launch EasyWare. When EasyWare is launched for the first time, you are prompted to choose the language and enter the software serial number. Enter the software serial number that is provided on the CD-ROM sleeve and then quit EasyWare.

13 EasyOne-CS Lithium Battery Replacement

This procedure is intended for use by trained electronic service technicians. It describes how to exchange the internal Lithium battery.

13.1 Background

The internal Lithium battery of the EasOne-CS has a lifetime of more than 5 years (designed to last up to 10 years). If the lithium battery is empty, the device shows an error #25 message. The battery is needed to hold the date & time and parts of the device configuration information which is stored in the RAM area of the RTC. If the battery is empty, this data is corrupt and leads to the above error. In this case, it is necessary to change this battery.

13.2 Environment

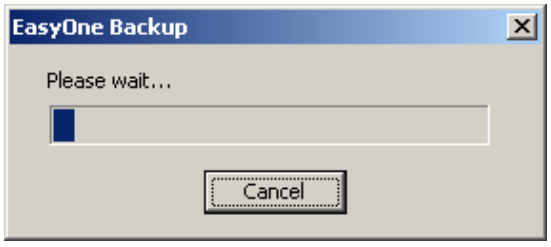
1. Windows PC with installed and working EasyOne-CS connection (Serial cradle, USB cradle or Screen-Connector)
2. Installed EasyWare greater or equal V02.04
3. Torx T8 / Allen key /hex key screw driver depending on serial number
4. Electrostatic save working environment for the device disassembly

13.3 Preparation (save database)

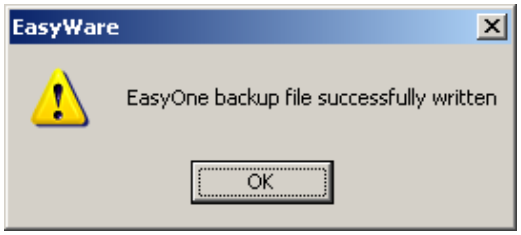
To make sure that no data is lost/altered, the internal EasyOne-CS database should be saved first. Please follow the below steps.

1. Start EasyWare by the link on the desktop
2. Switch EasyOne-CS on and press key sequence 1-3-5 when the below shown error screen appears. Enter the date & time if requested. Then the normal main menu should be shown.

3. Connect the EasyOne-CS to the PC (Device Connected is shown in the status line of EasyWare/ “PC interface active” on the EasyOne-CS screen)
4. Go to menu: File/Backup Device DB... And the following progress bar appears



5. The EasyOne-CS backup file will be written (takes several minutes) and the success is indicated by the following dialog



6. The backup file of the form EZ1BackupXXXXX_DateTime.txt
   - XXXXX: device serial number
   - Date: YearMonthDay
   -Time: HourMinute
   (e.g. **EZ1Backup40126_200506071607.txt)** is located in the folder where EasyWare has been started e.g. C:\programmfiles\ndd Medizintechnik\EasyWare

13.4 Battery exchange procedure

Please make sure that your working environment is electrostatic safe to avoid damage to the used electrostatic sensitive electronic components

- Open the front cover by removing the two main screws.
- Remove the printed circuit board (PCB)
  Do not remove the sensor tube (two additional screws)
- Remove the Lithium battery (see figures below)

- Insert only 3V BR 1225 batteries which are approved by ndd Medizintechnik AG (e.g. Panasonic 3V BR 1225)
- Make sure that the + Sign form holder and battery are matched.

- Enter the new battery by preventing any short circuit (use only your fingers)
- Insert the PCB back to the EasyOne-CS case.
- Attach the front half of the case (make sure no cable will be squeezed)

False

Correct

13.5 Restart EasyOne-CS

Switch the EasyOne-CS back on. The above described error screen (#25) should be shown. Do the steps as described before. If you are in the main menu, check that all records are there by going to View results. If you are sure that all records are there, the exchange is finished.

13.6 Restore database

Under normal conditions EasyOne-CS restores the database by it self (Please wait… screen after 1-3-5). Double-check the amount of stored records. If the “Please wait…” screen appears longer than ca. 3 minutes you can interrupt it by pressing the ESC key (hold 0 key for more than 2sec.). This is only possible for firmware versions ›= V02.14.00.00. If restore database failed, it will be necessary to restore the database manually. **This can only be done at ndd!**

14 EasyOne-CS board with sensor and housing parts Replacement

This procedure is intended for use by trained electronic service technicians. It describes how to exchange the internal board with sensor and how to change the housing parts.

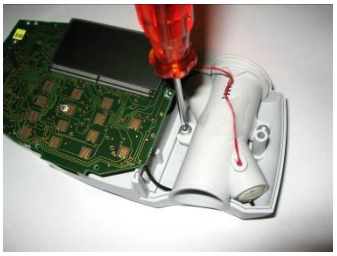
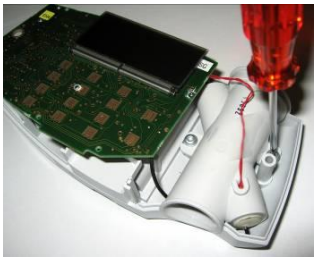
14.1 Background

If the sensors and/or the board fail, the complete board with the sensors has to be changed. If one housing part gets disturbed, change it following the description.

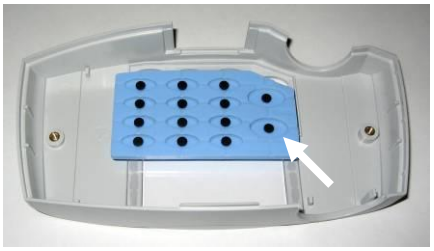
Please make sure that your working environment is electrostatic safe to avoid damage to the used electrostatic sensitive electronic components

- Open the battery door and remove the 2 AA batteries
- Open the front cover by removing the two main screws on the backside

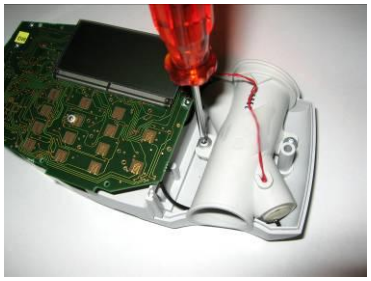
- Remove the board (no screws) so you can remove the sensor tube by removing the two screws

- When you only change the front you must not remove the board with the sensors, remove the keypad from the damaged front and put it into the new front part.

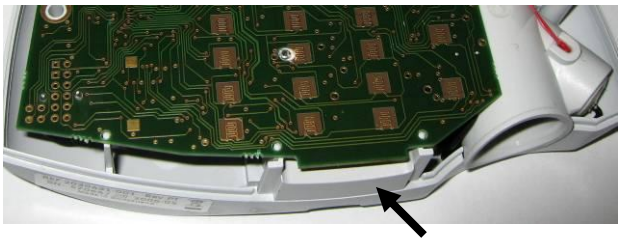


- When you change the board, remove the old one and replace it with the new one. Bring the sensor tube into position and screw it with the washers – be carefully, do not turn the screws to tight! Bring the board into position.



- Put the front part with the keyboard back on the instrument in that way that the window is placed over the LCD display and that the front fits tight on the back cover
- Turn the instruments (front at the bottom) and turn the screws in. The holes in the hook sleeves must be in the right position, look to the left and right side of the instrument

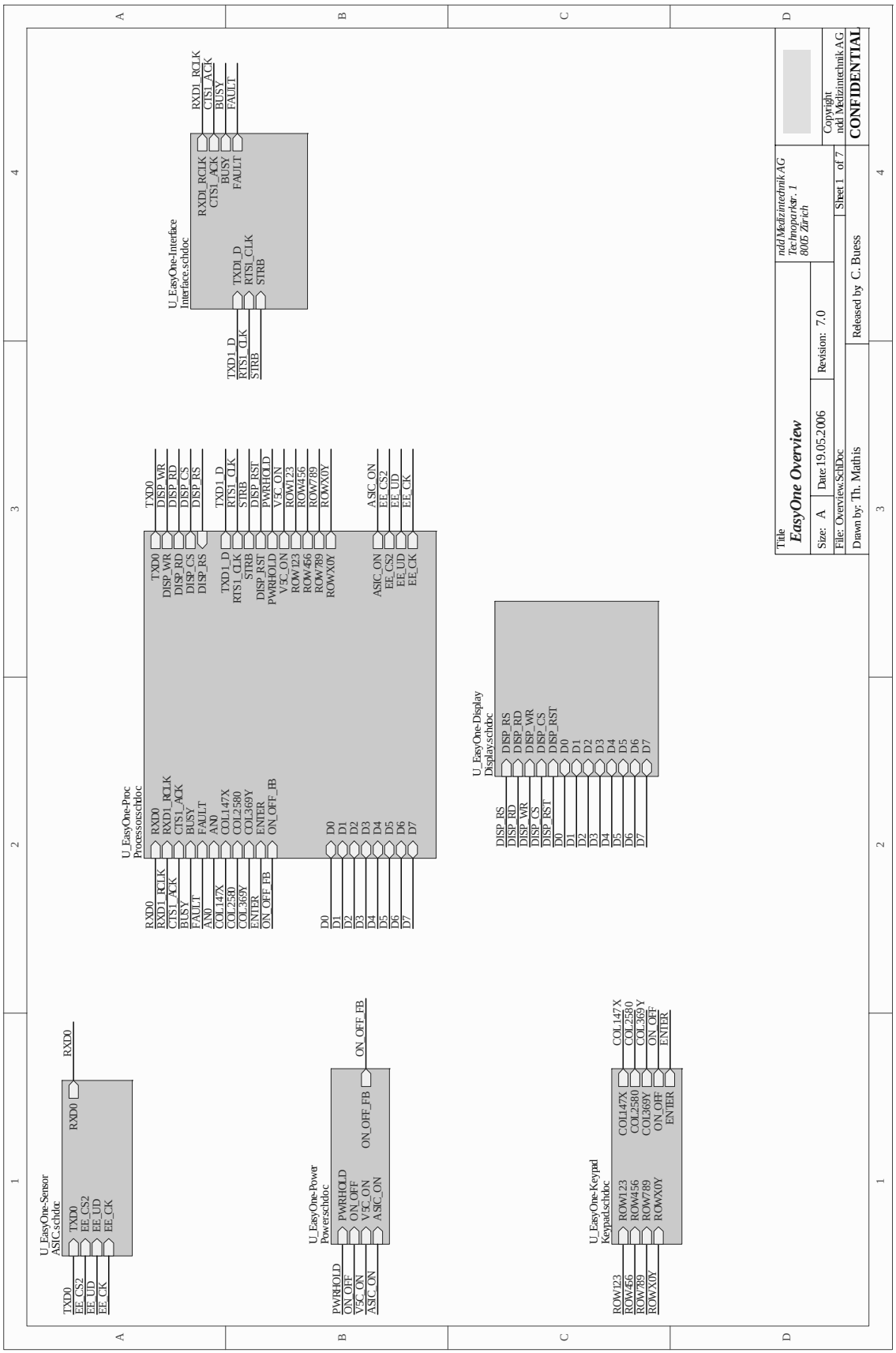
- When you change the rear half of the housing, please remove the pocket and the serial number label (silver label) from the old housing part and but the pocket into the rear half and glue the label at the same position on the new rear half part.

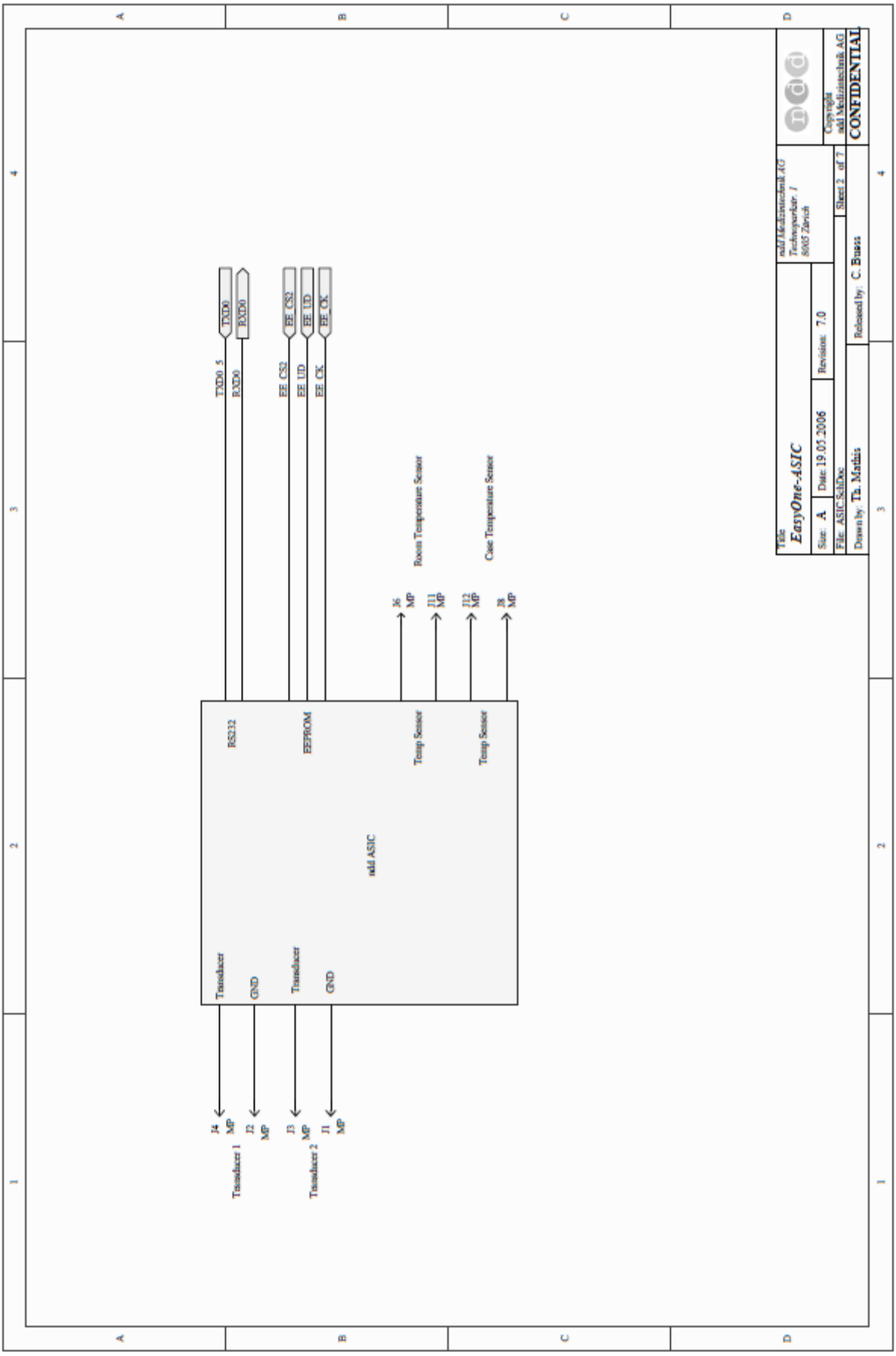


- When you change the board with sensor, remove the old label and glue the new delivered one onto the rear half.
- Put in the 2 AA batteries, close the battery door

15 Appendix

15.1 Schematic Diagrams

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EE_I/D
EE_CK
TXD0_5
RXD0
EE_CS2
EE_I/D
EE_CK
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Case Temperature Sensor
J6 MP
J11 MP
J12 MP
J8 MP
RS232
EEPROM
Temp Sensor
Temp Sensor
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Transducer
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J4 MP
J2 MP
J3 MP
J1 MP
Transducer 1
Transducer 2
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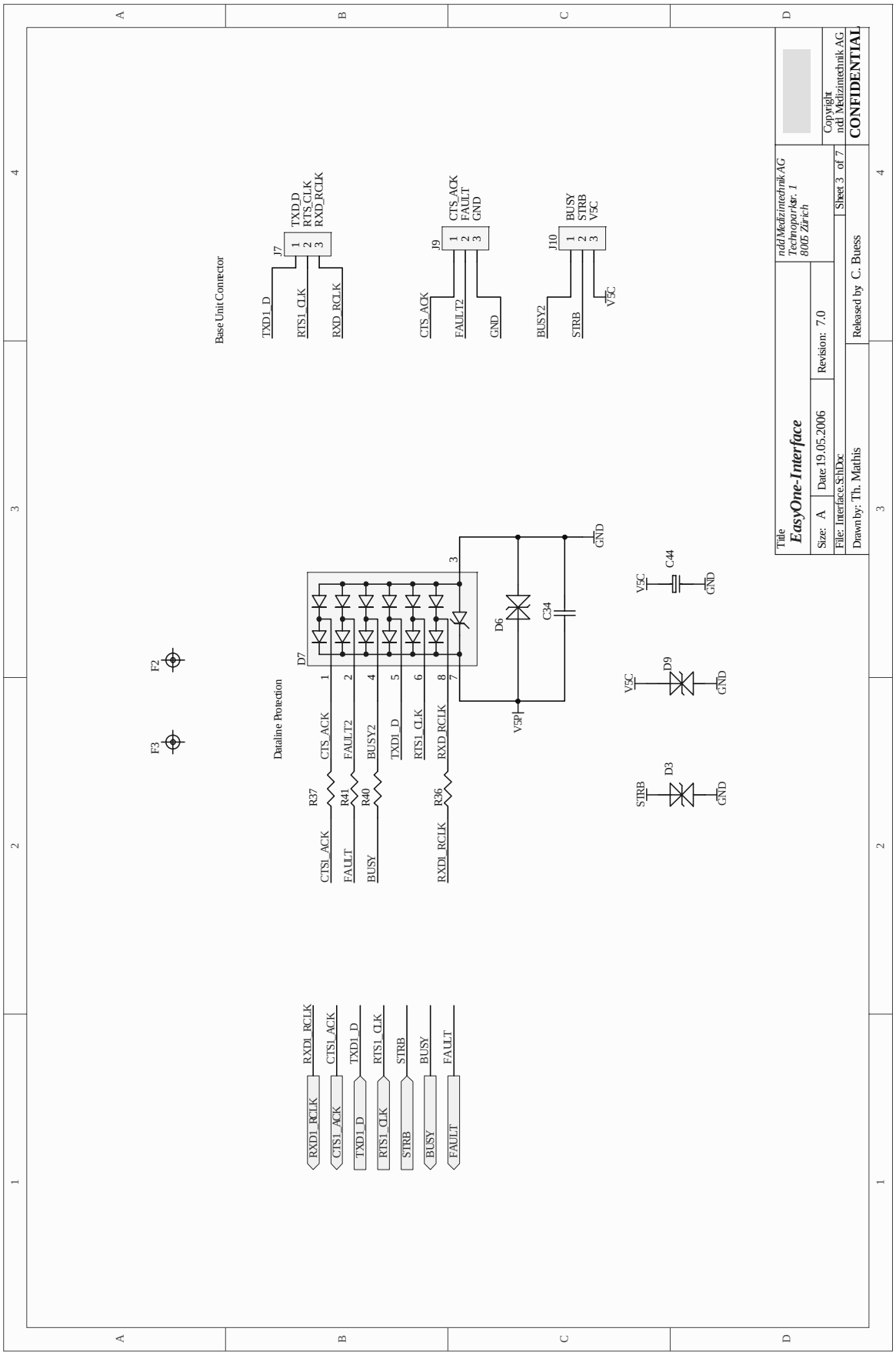
Base Unit Connector
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TXD1_D
RTS1_CLK
RXD_RCLK
TXD_D
RTS_CLK
RXD_RCLK
J9
CTS_ACK
FAULT2
GND
CTS_ACK
FAULT
GND
J10
BUSY2
STRB
V5C
BUSY
STRB
V5C
Dataline Protection
D7
R37
R41
R40
R36
CTS1_ACK
FAULT2
BUSY2
TXD1_D
RTS1_CLK
RXD_RCLK
CTS1_ACK
FAULT
BUSY
RXD1_RCLK
D6
C34
V5P
GND
C44
V5C
GND
D9
V5C
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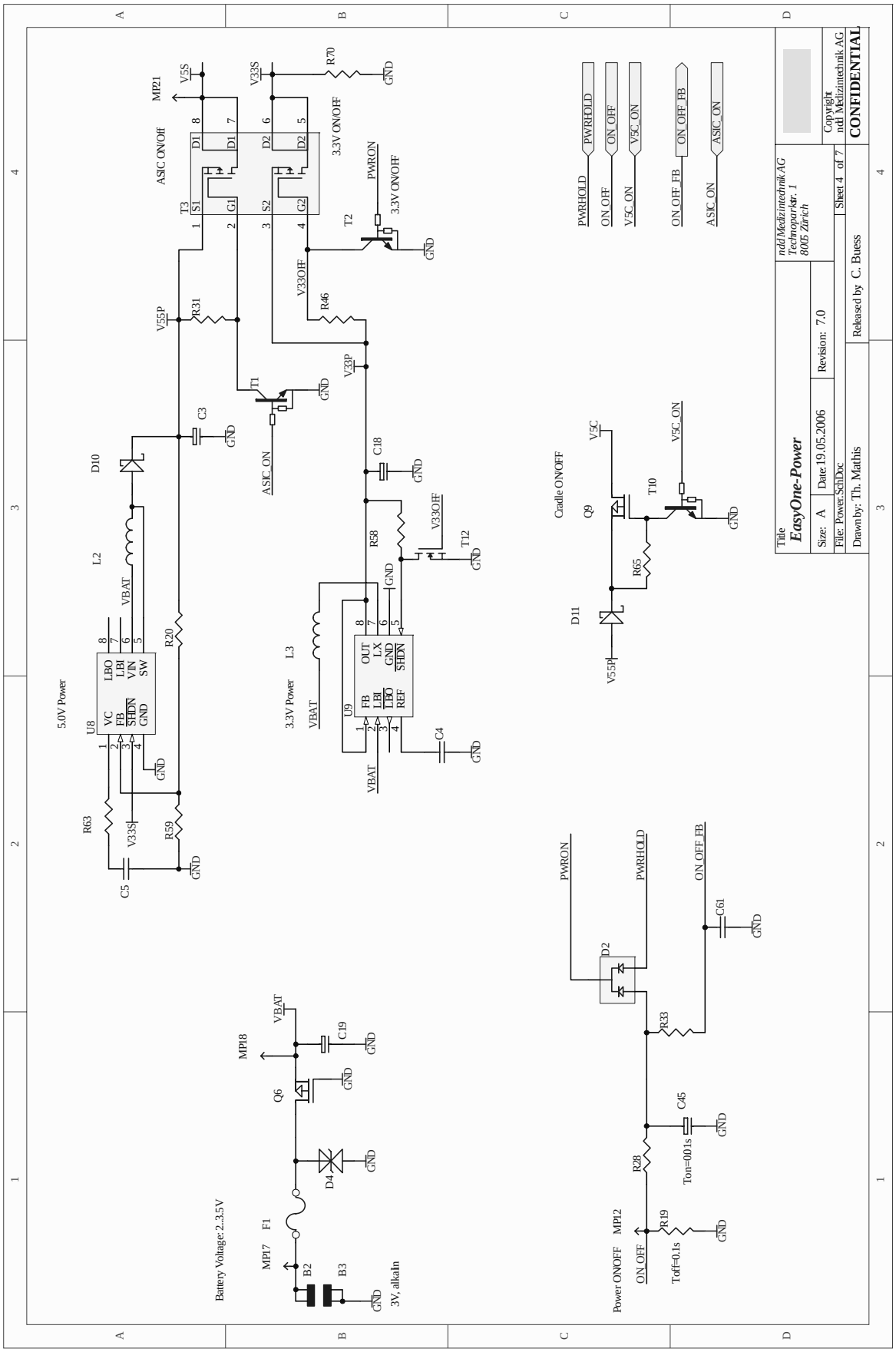
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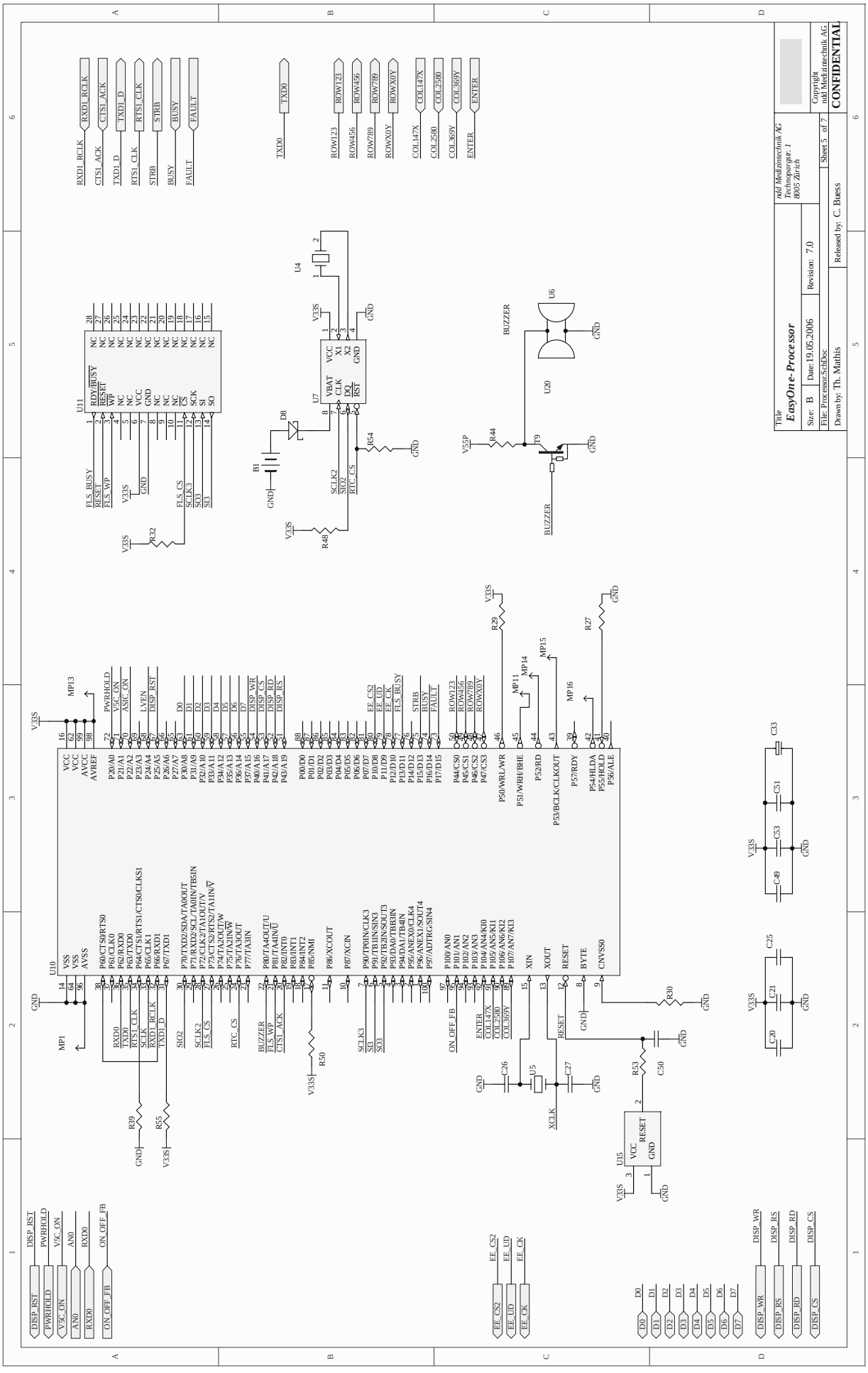
5.0V Power
3.3V Power
Cradle ON/OFF
Power ON/OFF
Battery Voltage: 2..3.5V
3V, alkaln
ASIC ON/Off
3.3V ON/OFF
PWRHOLD
ON_OFF
V5C_ON
ON_OFF_FB
ASIC_ON
VBAT
GND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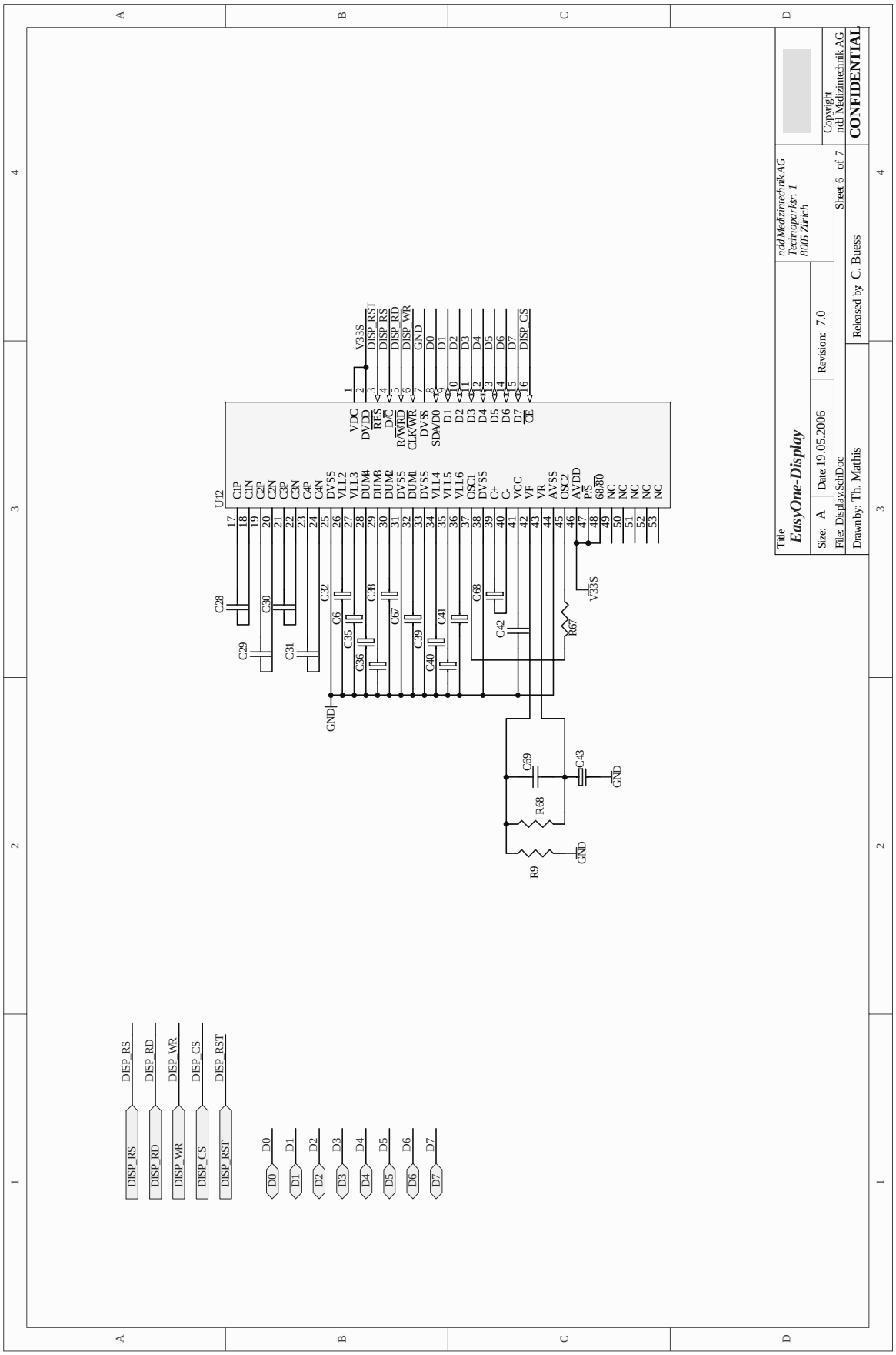
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R68
R9
V33S
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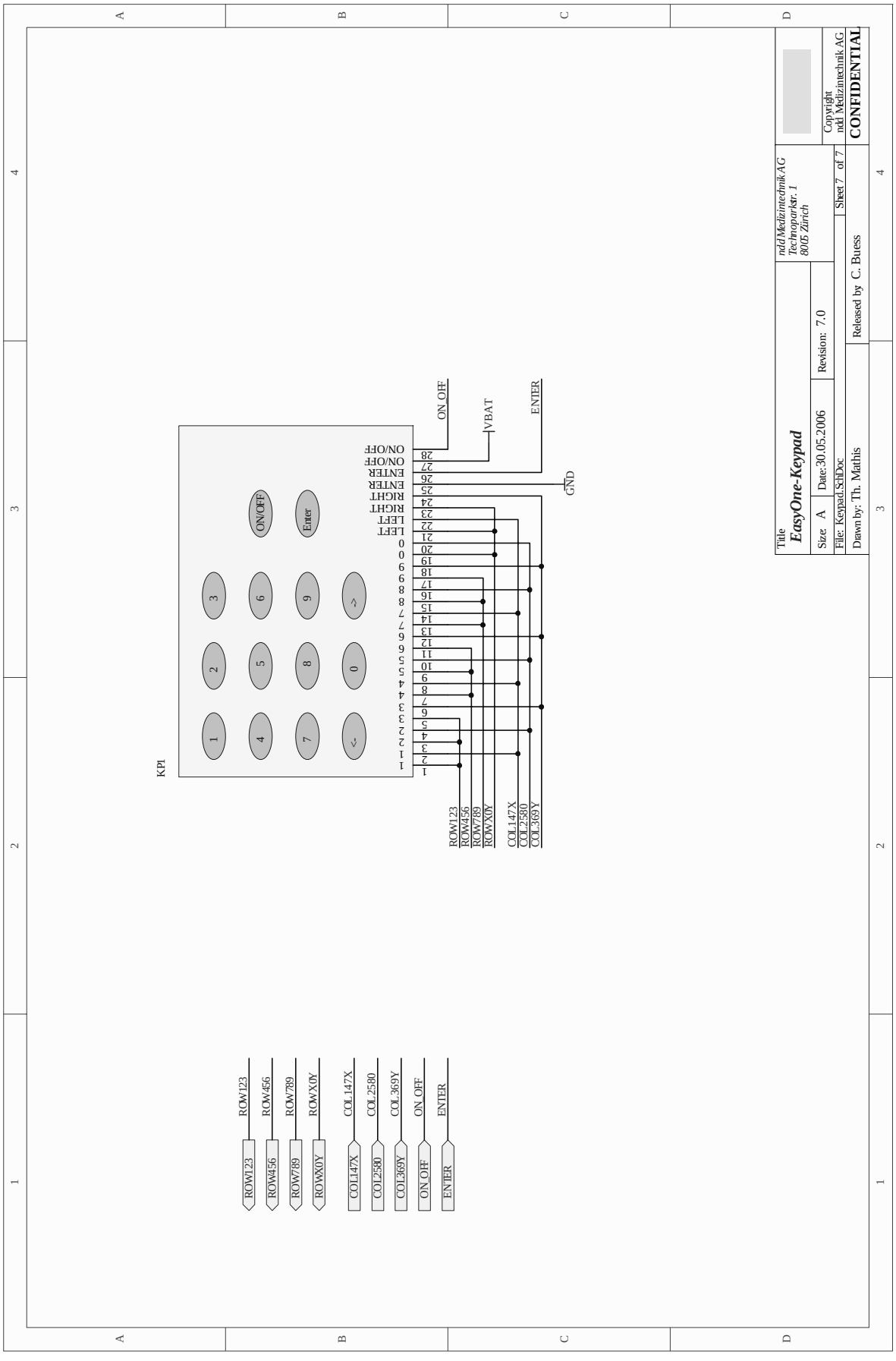
D7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8
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Enter
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ENTER
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