

Delivery specification COBAS-Reader 8000

Revision: 1.1.1





Document approval signatures

Responsible for definition and writing of specification:

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Approval	RD	S. Rosenblatt		





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1 General description

The COBAS-Reader 8000 is a customer specific adopted RFID reader based on TagStar's TS1415 reader technology. It is designed for the use in a Roche / Hitachi C701/702 system.

1.1 Supported RFID chips

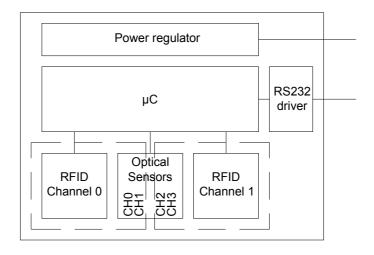
Following ISO 15693-3 compatible chips are supported by the COBAS-Reader 8000 RFID reader.

Due to the project definition the COBAS reader supports the following RFID chip:

NXP I-Code SLI, the following documents are attached:
 I-Code SLI SL2 ICS20, Smart Label IC, Short Form Specification, April 2002 (Appendix 1)
 I-Code SLI SL2 ICS20, Smart Label IC, Functional Specification, January 2003 (Appendix 2)

1.2 Functional description

The COBAS-Reader 8000 has a two channel detection system consisting of a RFID antenna and two optical sensors each. The optical sensors are used to detect the rotational orientation of a cassette placed below the reader unit. Therefore the cassettes are labelled with a black/white coloured RFID label. At the detection process the RFID reader reads the data of the transponder which is inserted into the RFID label. To control the cassette orientation both optical sensors measure the reflected light, which indicates the black and white label area. Depending on the reflection value the host system could decide if the cassette is inserted in the correct orientation or turned at 180°.



Drawing 1: Block diagram of COBAS RFID reader



1.3 Model, Manufacturer

The COBAS-Reader 8000 can be ordered at etifix at the following order code: COBAS-Reader 8000

The reader electronic unit consists of a two channel RFID reader main board, with two external detection units. These detection units carry an adopted RFID antenna and two optical sensors for the position detection of labelled cassettes. The electronic unit is assembled into a housing provided by etifix.

The whole production of the COBAS-Reader 8000 unit will be done under the responsibility of etifix and a subcontractor which are ISO 9001:2000 certified. The subcontractor is qualified and trained to meet the special requirements of RFID reader production. (Appendix 12, 13)

1.4 Labelling

Each COBAS-Reader 8000 is labelled with different identification and security labels. The following picture shows the position of each label:

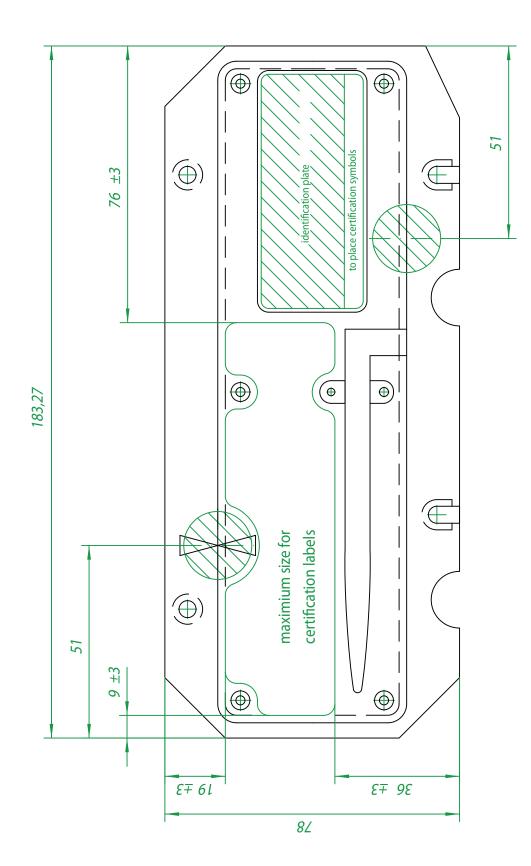


Picture 1: Labelling of COBAS RFID reader

Position of labels on cassette:

The position of all labels on the cassette are shown on etifix drawing no. 7-50-1-1-2-1

Is on the top side of the RFID reader position of label



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Identification label

Example of a label



The factory number is defined by etifix.

The serial number has the following syntax: JJMM-xxxx

JJ: Year of productionMM: Month of production

xxxx: Serial number of the reader, continuously increased

Security labels



Certification labels

Depending on national rules extra certification labels are applied on top of the reader housing. Sample of a label:





2 Applied standards and regulations

The COBAS-Reader 8000 is conformal to the following radio regulations and standards:

- **Europe (CE)**: EN 300 330-1 V1.3.1 (2001-06), EN 300 330-2 V1.3.1 (2006-04), ETSI EN 301 489-1 V1.6.1 (2005-09), ETSI EN 301 489-3 V1.4.1 (2002-08), EN 60950-1:2006, EN 50364:2001
- US: FCC Code of Federal Regulations, CFR 47, Part 15, Sections 15.205, 15.207, 15.215, 15.225
- Canada: Industry Canada Radio Standards Specifications RSS-Gen Issue 2, Section 7.2.2, RSS-210 Issue 7, Sections 2.2, 2.6, A2.6 (Category I Equipment)
- Japan: ARIB standard T82 V1.1

The COBAS-Reader 8000 will be compliant to the upper mentioned standards.

For the in appendix "Country list for registration RFID readers 0-series and series for c701/702" (see Appendix 3) listed countries a compliance certification will be applied for. Therefore additional standards will be applicable, but are not listed under this chapter. The compliance measurement and appliance will be done by CETEOM ordered by etifix.

Additional applicable standards:

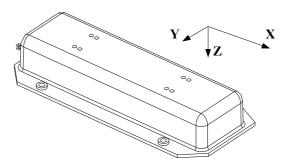
- compliant to the RoHS regulations (Appendix 4)
- relevant components of the COBAS-Reader 8000 are UL recognized (Appendix 5)

Compliance certifications for national regulations are in progress of application and are not appended to the document.



3 Specification

The following reader parameters refer to the below shown coordinate system:



Drawing 2: Coordinate system for measurement values

3.1 Power supply

Value	Symbol	Min	Max	Unit
Supply voltage (at external connector)	V	4,75	5,25	V_{DC}
Max. ripple on supply voltage	V_{ss}		150	mV_{PP}
Current consumption, standby 1)	I standby		70	mA
Max. current consumption ²⁾	I max		350	mA
Reader reset threshold voltage	V _{Thres}	4,60	4,70	V_{DC}

Table 1: Power supply ratings

- ^{1).} Measurement conditions: V = 5V, both RF channels switched off, all 4 LED's of the optical sensors are switched off
- $^{2)}$ Measurement conditions: V = 5V, both RF channels switched on, all 4 LED's of the optical sensors switched on

Attention: Supply voltages higher than 5,5 V might permanently damage the circuitry of the COBAS-Reader 8000 and have to be avoided.

The COBAS-Reader 8000 has no internal fuses or any inrush current limitation. It is recommended to integrate an appropriate protection circuit into the power supply line to protect the reader and surrounding hardware against damage in case of failure or over voltage. A suppressor diode is integrated into the power supply circuitry. Specific data of the suppressor diode see appendix "1.5SMC6.8AT3-D" (Appendix 6).

The circuitry is operates with an internally stabilized voltage for optimum and stable operation.

Behaviour of the COBAS-Reader 8000 at different supply voltages see at Appendix 7.



3.2 RFID data

Value	Symbol	Min	Max	Unit
RFID Frequency (typical)		13,56		MHz
Modulation degree according to ISO 15693		10	0%	%
Data transfer rate Tag <-> Reader according to ISO 15693		a coding 1 ou 26,48 kBit/s		
RFID Output power @ 50 Ω termination	P _{HF}	70	90	mW
Read distance 1)	d_{Peak}	0	20	mm
Minimum distance between two labels (centre to centre of label) to avoid cross talking	d_{LL}	40		mm

Table 2: RFID measurement values

Measurement conditions: V = 5V, Transponder size = 20x10mm, Chip I-Code SLI
Transponder is converted to a label and placed on top of cassette
Read distance is measured from housing of reader to top surface of cassette
The transponder is readable over the whole operation distance between reader housing and the specified maximum read distance

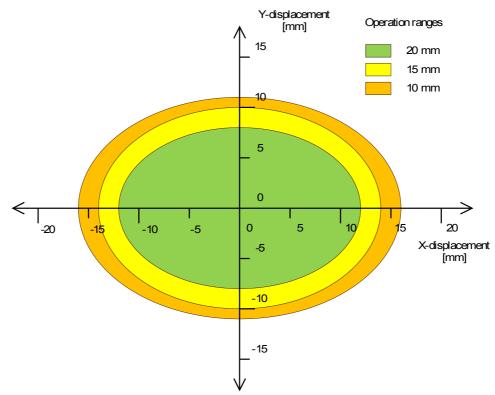


Diagram 1: Typical operation distance depending on label displacement from reader antenna centre



The typical field strength of the COBAS-Reader 8000 in a distance of 13 mm from the reader housing has the following characteristic:

Field strength COBAS RFID reader

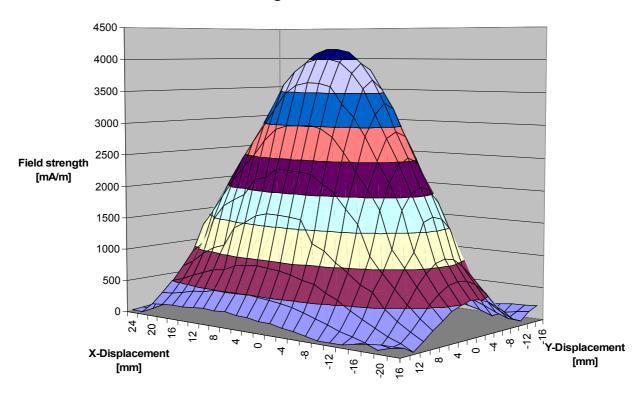


Diagram 2: Typical field strength in dependence of position under the reader measured at a distance of 13 mm measured from bottom of reader housing



3.3 Optical sensors

Value	Symbol	Min	Max	Unit
Current consumption per Sensor channel	I_{Sensor}	25	35	mA
Wave length of sensor light	λ	629	661	nm
Response value "white" 1)	RV _{white}	250		Digits
Response value "black" 2)	RV _{black}		100	Digits
max. displacement in X-axis 3)	d_{X}		3	mm
max. displacement in Y-axis 3)	d_{Y}		5	mm
Settling time of sensors (measurement delay after LED is switched on)		5		ms

Table 3: Optical sensor values

All values are measured with both channels at one detection position switched on simultaneously. The following commands are used: WriteOutput and ReadAnalogInput according to the document "COBAS interface protocol v1.5"

 $^{^{1)}}$ Measurement conditions: V = 5V, distance between sensor and white reference surface = 13 mm

Measurement conditions: V = 5V, distance between sensor and black reference surface = 13 mm

Measurement conditions: V = 5V, distance between sensor and cassette = 13 mm; transponder label applied 2,5mm out of cassette centre (white area at cassette border)



3.4 Environmental conditions

Value	Symbol	Min	Max	Unit
Operation temperature range	T _{Operation}	5	+35	°C
Storage temperature range	$T_{Storage}$	-20	+75	°C
Requested Relative humidity for storage and operation (not condensing)		5	95	%
Requested protection against mechanical vibration in X/Y/Z direction at full operation 1)			2,5	m/s ²
Normal operation after single shock in X/Y/Z direction ^{1,}			294	m/s ²
Housing protection class against intrusion of rigid particles and liquids (DIN EN 60529)			IP 20	

Table 4: Environmental conditions

Note: The COBAS-Reader 8000 housing is only sealed against condensing of water at the bottom of the reader housing at normal assembly orientation in the rotor housing. No special protection against water intrusion from all other sides is provided.

Because Hitachi has confidential internal standards the environmental tests are specified as follows:

• Rapid Change of Temperature according to EN 60068-2-14

-20°C / +75°C test temperatures

2h exposure time for upper and lower temperature

5 cycles

<10 sec. transportation time from one chamber to the other

COBAS-Reader 8000 off during test

• Cold storage according to EN 60068-2-1

+5°C exposure time

16h exposure time

1 K/min temperature changing speed from RT to test temperature

COBAS-Reader 8000 on during test

• Dry heat according to EN 600068-2-2

+35°C exposure temperature

16h exposure time

1 K/min temperature changing speed from RT to test temperature

COBAS-Reader 8000 on during test

¹⁾ Exact specification of mechanical vibration and shock tests see below



• Damp heat, steady state, according to EN 60068-2-78

30°C exposure temperature

5% relative humidity

16h exposure time

1 K/min temperature changing speed from RT to test temperature

COBAS-Reader 8000 on during test

• Damp heat, steady state, according to EN 60068-2-78

30°C exposure temperature

95% relative humidity, non condensing

16h exposure time

1 K/min temperature changing speed from RT to test temperature

COBAS-Reader 8000 on during test

• Vibration (sinusoidal) according to EN 60068-2-6

5 Hz lower frequency

200 Hz upper frequency

0,75 mm displacement amplitude

0,25 g acceleration

9,2 Hz cross-over frequency

1 octave/minute frequency sweep

10 cycles per axis, 3 axis tested (X;Y,Z)

COBAS-Reader 8000 on during test (normally off, on requested by HHT)

• Vibration (sinusoidal) according to EN 60068-2-6

5 Hz lower frequency

200 Hz upper frequency

3,5 mm displacement amplitude

1,6 g acceleration

10,8 Hz cross-over frequency

1 octave/minute frequency sweep

10 cycles per axis, 3 axis tested (X;Y,Z)

COBAS-Reader 8000 on during test (normally off, on requested by HHT)

Shock according to EN 60068-2-27

30 g acceleration

11 ms shock duration, half-sine pulse shape

3 shocks per direction, 6 directions tested ($\pm X$, $\pm Y$, $\pm Z$)

COBAS-Reader 8000 off during test

• Free fall according to EN 60068-2-32

1 procedure

300 mm fall height

1 tests per defined orientation (5 fall tests)

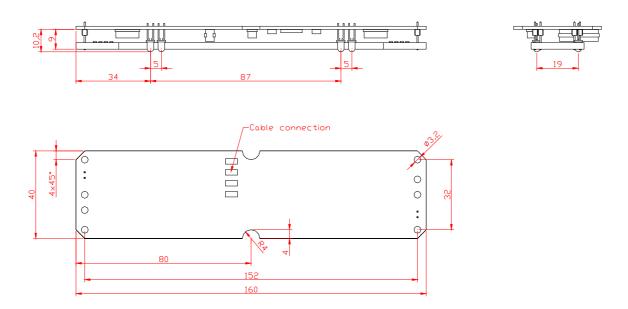
COBAS-Reader 8000 without packaging

COBAS-Reader 8000 off during test



3.5 Dimensions

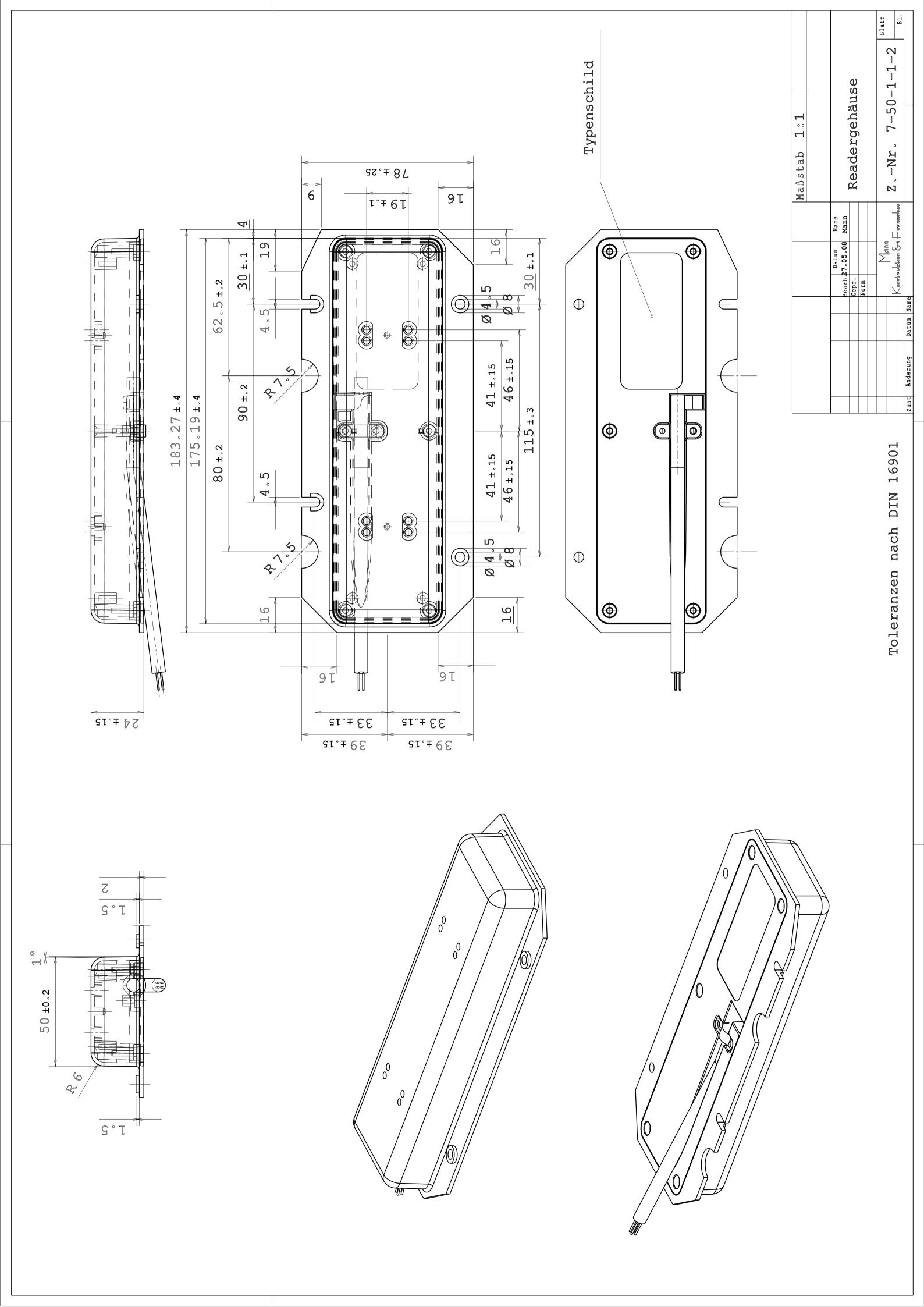
The PCB-Board of the COBAS-Reader 8000 has the following dimensions:



Drawing 3: Final assembly of COBAS RFID reader electronic

3.6 Dimensions of reader housing

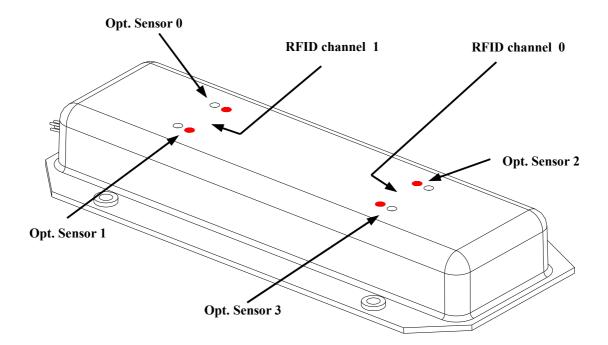
The reader housing is specified in drawing no. 7-50-1-1-2 (Document "Reader housing").





3.7 Channel positions

For correct addressing of the RFID-channels and optical sensor channels please pay attention to the following drawing:



Drawing 4: Side view of COBAS RFID reader (red dots indicate position of LED)



3.8 Connector

The COBAS-Reader 8000 comes with a 800 mm long cable for the connection to the external host.

Cable type: UNITRONIC LiYCY UL/CSA 4x AWG22/7,

Manufacturer LAPPKABEL, order code 0044704

fire-retardant according to IEC 60332-1-2, UL VW1, CSA FT1

see Appendix 8, 9

Connector type: AMP D-2100, Product code 1318119

Drawing of cable: see attachment "Cable_v1.6.pdf" (Appendix 10)

Pin assignment:

Pin	Name	Direction	Description
A1	+5V	PWR	Positive supply voltage
B1	GND	PWR	Reference voltage level for power supply and serial communication
A2	RxD	In	Receive signal from host
B2	TxD	out	Transmit signal to Host
A3			Shorted with cable
В3			- Shorted with cable

Table 5: Pin assignment cable connector

Maximum pull force at the cable: 40 N

3.9 Serial interface parameters

The data between the COBAS-Reader 8000 and a host system are transmitted via a serial interface. The voltage levels at the serial interface is fixed to V24-level standard, e.g. for communication with a PC.

Interface parameters:

Baud rate	19.200
No of Bits	8
Stop bit	1
Parity	N
Handshake	No hardware or software handshake



3.10 Host communication protocol

The communication protocol between a host system and the COBAS-Reader 8000 is defined in the document "COBAS Interface Protocol v1.5" (Appendix 11)

3.11 Life time

The analysis of the critical components and the corresponding circuitry of the COBAS-Reader 8000 resulted in an expected life time of more than 16.000 hours of operation.

4 Packaging

Every COBAS-Reader 8000 is packed into an ESD proof carton box, protected with ESD save foam against mechanical shocks. Each carton box is labelled with a label showing the product name and the serial number.



Picture 2: Packaging of COBAS RFID reader



Picture 3: Carton box with labelling



5 Embargoed countries

According to the information given from Mr. Martin, Head of division for Electronics, Optics and Sensors (phone: 06196 / 908 - 788) at the Federal Office of Economics and Export Control in Germany are the COBAS-Reader 8000 not restricted in any countries if they are used for medical applications as they are designed for. The end user has to ensure that the COBAS-Reader 8000 are only used for their intent application in the COBAS 8000 systems.

6 Installation notes

No special ESD prevention is required to assemble the COBAS-Reader 8000. It is recommend to use a ESD wristband when you unpack the reader and connect it to the host system. The system power has to be switched off prior to the assembly.

Be aware of the following possible environmental effects when your are installing the COBAS-Reader 8000 into a device. Also the transponders might be effected by:

- Nearby existing metal objects like housings, shielding and also PCB-boards with large ground plates.
- EMC effects from cables
- EMC effects from magnetic fields.

Metal surface in direct vicinity of the active internal antenna will detune the antenna and thus have a direct influence to the operating distance. Increase the distance between the antenna and the metal layer to the possible maximum for least influence.

Communication between the reader and a transponder can never pass through a metal layer.

The optical sensors might be influenced (reduced) by condensed water on the housing of the LED / detector components. A transparent medium should be placed on the rotor jacket cover for preventing water condensing at the optical sensor area. The medium should be selected carefully and has to be transparent for red light emitted by the LEDs.

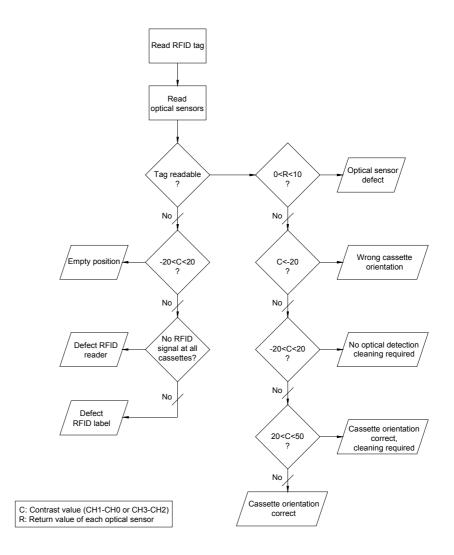
Contamination by deposition of reactants on the optical sensors will reduce the reflection values for the white and black label surface until no distinction can be made. Please take care that the sensors are periodically cleaned.

The COBAS-Reader 8000 housing is designed to protect the reader electronics against humidity and water condensation from the reagent rotor side. Please take care for a good sealing of the COBAS housing against the rotor cover to prevent moisture / condensed water getting into the housing through the cable outlet.



6.1 Recommended software algorithm for cassette position detection

Based on several tests done at Roche Mannheim and Roche Penzberg the following procedure for cassette position detection is recommended. This algorithm is able to distinguish between different states.:



Picture 4: Program flow for analysis of optical sensor output

Depending on further evaluation the decision criteria for valid sensor signals and valid differences might have to be adopted.



7 Possible interactions between the COBAS-Reader 8000 and the host system

Several different failure modes could have an impact on the functionality of the host system. The COBAS-Reader 8000 is designed according to best knowledge to avoid any negative interactions with an host system. All electrical interfaces to the host system are designed in conformance to existing standards. The following table lists possible failure modes and methods to prevent defects on the host system.

Failure mode / possible influence	Protective measures
Short circuit on reader board at the power supply	Integration of an appropriate protection circuit into the power supply which limits the supply current to 350mA during operation
Failure at the RS232 interface, like short or open wires	The COBAS-Reader 8000 uses an RS-232 interface driver which is according to industrial specifications
Data failure inside the COBAS machine due to EMC / EMV	The reader will be qualified according to international standards as listed in chapter 2 to minimize the risk of potential influences.
Impact of the emitted RFID field to the measurements	This effect can't be estimated and depends strongly on the measurement methods used. Switch off the RFID antennae of the reader before starting the measurements
Malfunction of the optical detection due to humidity condensation	Condensed humidity reduces the responses values of the black and white label area. Therefore software could distinguish between both colours by measuring the relation/difference of both responses values.
	Threshold values for contrast and absolute sensor values for black and white label areas have to be defined.
Malfunction of the optical detection due to contamination by reactants	Periodical manual cleaning of the optical sensors by service personal or operators
	Threshold values for contrast and absolute sensor values for black and white label areas have to be defined.
Malfunction of the optical detection due to HF field	Due to the mechanical design of the detection channels a powered HF field has a direct influence to the response values. For save measurements it is strongly recommended to switch the appropriate HF channel off before the optical sensors are read out.
Interference of optical sensors	The interferences between the optical sensors CH0/CH1 or CH2/CH3 are at an absolute minimum and have no impact to the measurement.



8 Product warranty

etifix provides customer assistance in various technical areas, but does not have full access to data concerning the use and applications of customer's products. Therefore, etifix assumes no liability and is not responsible for customer applications or product or software design or performance relating to systems or applications incorporating etifix products.

etifix assumes no liability and is not responsible for infringement of patents and/or any other intellectual or industrial property rights of third parties, which may result from assistance provided by etifix. The electronic circuitry and reader firmware has been checked for critical solutions and routines. etifix is not liable for infringements of patents and/or any other intellectual or industrial property rights of third parties resulting out of the usage in the COBAS analysis system.

etifix products are not designed, intended, authorized or warranted to be suitable for life support applications or any other life critical applications which could involve potential risk of death, personal injury or severe property or environmental damage. A critical component is a component used in a life-supporting device or system whose failure can reasonably be expected to cause the failure of that life-support device or system, or to affect its safety or effectiveness of that device or system. Life support devices or systems are intended (a) to be implanted in the human body, or (b) to support and/or maintain and sustain human life. If they fail, it is reasonable to assume that the health of the user may be endangered.

The product warranty is defined by governmental law and in etifix's "General Conditions for the supply of products and services.



9 List of appendixes

Appendix No.	Description
1	I-Code SLI SL2 ICS20, Smart Label IC, Short Form Specification, April 2002
2	I-Code SLI SL2 ICS20, Smart Label IC, Functional Specification, January 2003
3	Country list for registration RFID readers 0-series and series for c701/702
4	RoHS compliance certificate
5	UL Compliance certificate
6	Data sheet 1.5SMC6.8AT3-D
7	Behaviour of the COBAS-Reader 8000 at different supply voltages
8	Data sheet of cable
9	Ohmic resistance of cable
10	Cable_v1.6 specification
11	COBAS Interface Protocol v1.5
12	ISO 9001 certificate etifix
13	ISO 9001 certificate Zollner



10 Document revisions

Datum	Version	Status
27.11.07	0.1	1 st draft version
31.03.08	0.2	Extension with additional requested information
	0.3	Internal working paper
15.07.08	0.4	Purpose: Draft as appendix to the "Einzelentwicklungsvertrag"
		§1: Changes in overall description of product, added block diagram and identification plate layout
		§2: Extension of applied standards
		§3: General changes at all sub chapters
		§4. Extensions
		§5: Extensions
		§6: Extensions
		§7: Extensions
		§8: Extension about raw material discontinuation
	0.5	 §1.4: Change of label samples, extended explanation §3.1 Change of power supply data §3.2 Change of RFID data §3.3 Change of optical data §3.4 Description of environmental tests §3.5 Drawing of reader electronics assembly §3.7: Correction of optical sensor position, additional 3D drawing §3.8 Change of cable length to 800mm (future deliveries)
08.08.08	1.0	Public document for first shipment of COBAS-Reader 8000 (pre- production)



Datum	Version	Status
15.08.08	1.1	 §1.4: Added picture of labelled reader §2: Sentence about risks of third country certification removed, Canada added §3: Drawing with coordinate system showing axis of measurement values added §3.1: Change of data, change of recommended fuse §3.2: Change of data, read area values at 80% of read range deleted Diagram with operation range in dependence of position added §3.3: Change of data, digram showing valid reflection values in dependence on position above label added §3.4: Standard for IP protection class added, editorial changes §3.6: editorial changes §3.8: Maximum pull strength of cable fixture added §3.10:Release info of COBAS interface protocol document added §4: Secondary packaging removed §6: ESD handling precautions added §7: Exchange TagStar with etifix
	1.2	Working paper, not released
22.10.2008	1.3	Added Reviewer and Approval list §1.2: Correction on position of label on cassette §1.3: Correction of product name §1.4: Change of picture of labelling Added drawing about position of labels §2.0: Intern. Compliance certifications are excluded to this document §3.1: Added behaviour at different supply voltages Added notice about over voltage §3.2: Change of RF output power Adding diagram of HF field strength §3.3: Change of X/Y limits of acceptable label displacement Adoption of black/white limits to new label surface Sensor values measured simultaneously §3.6: Implementation of housing drawing §3.7: Removed drawing form bottom side, added LED position at optical sensors §3.8: Interface cable drawing changed from v1.2 to v1.4 (length tolerance, mounting ring, additional pins A3, B3) §3.10: Changed document version of interface protocol to 1.5 §3.11: Added topic Expected life time §4: Added pictures about packaging §5: Embargoed countries (none) §6: Editorial change at water condensation protection §7: Adopted value for recommended external fuse at power line Definition of threshold values recommended §8: Extension of intellectual property rights and exclusion of life supporting devices §9: Added topic Table of appendixes



Datum	Version	Status
05.02.2009	1.4	 General name change of the reader to COBAS-Reader 8000 (change from development project name to product name) §1.2: Remove over voltage protection from block diagram Wording misleading, see chapter 3.1 §1.4: Exchange of identification label to newer design (corrected max. current consumption 300 → 350mA) §2: Extension and correction of radio regulations and standards according to granted certificates §3.1: max. standby current consumption changed from 55mA to 70mA caused by review of first 150 readers. Change of wording for over voltage protection §3.4: Change of Damp heat testing standard from sub part 30 (dynamic humidity change during test) to sub part 78 (static humidity during test) as qualification test have been done and certified. §3.11:Change Expected life time → Life Time §6.1: Added chapter: Recommended software algorithm for cassette position detection §7: Change of wording for protective measures against short circuit and failures at communication interface
10.02.2009	1.4.1	 §1.4: Correction of identification plate picture (same plate as shown in other pictures used in this document) §3.1: Removed annotation about Reader reset threshold voltage Voltage will be measured at production testes §3.2: Removed annotation "Not verified at mass production" at diagram 1 and diagram 2 §3.8: Removed annotation "Not verified at mass production" at value for maximum pull force applied to the cable § 8: Removed clause about discontinuation of raw material. Has to be defined in delivery contract. Removed misspelling in sentence about critical solutions and routines.
17.02	1.5	Removal of HHT from the list of document approvals §3.1: Misleading wording about suppressor diode deleted