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Delivery specification
COBAS RFID Reader

Revision: 1.1

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1 General description

The COBAS read/write reader module 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

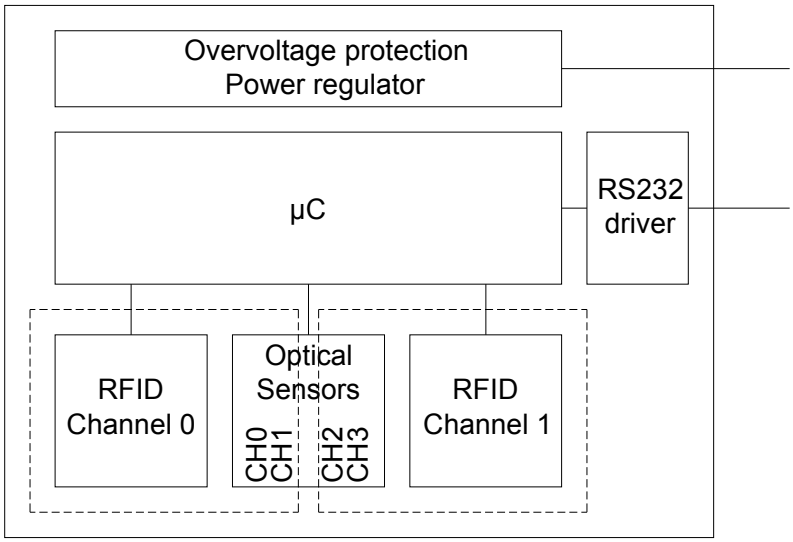
Following ISO 15693-3 compatible chips are supported by the COBAS reader.

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
  I-Code SLI SL2 ICS20, Smart Label IC, Functional Specification, January 2003

1.2 Functional description

The COBAS RFID reader 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 centre of the cassette. 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

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1.3 Model, Manufacturer

The COBAS RFID reader module can be ordered at etifix at the following order code:

COBAS RFID Reader

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 unit will be done at at ISO 9001:2000 certified subcontractor which is qualified and trained to meet the special requirements of RFID reader production.

1.4 Labelling

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

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Identification label

The factory number is defined by etifix.

The serial number has the following syntax: JJMM-xxxx

JJ: Year of production
MM: Month of production
xxxx: Serial number of the reader, continuously increased

Security labels

Certification labels

Depending on national rules extra certification labels are applied to the top of the reader housing.

Sample of a label:

2 Applied standards and regulations

The COBAS reader is conform to the following radio regulations and standards:

- **Europe (CE)**: EN 300 330-1 V1.3.1, EN 300 330-2 V1.3.1, EN 301 489-1 V1.6.1, EN 301 489-3 V1.4.1, EN 60950-1:2006, EN 50364:2006
- **US:** FCC Rules, Part 15, Subpart C, Section 15.225
- **Canada:** RSS-210 A2.6, RSS-GEN
- **Japan:** ARIB standard T82 V1.1

The COBAS RFID reader 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” 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
- all used electric/electronic components of the COBAS RFID reader are UL listed

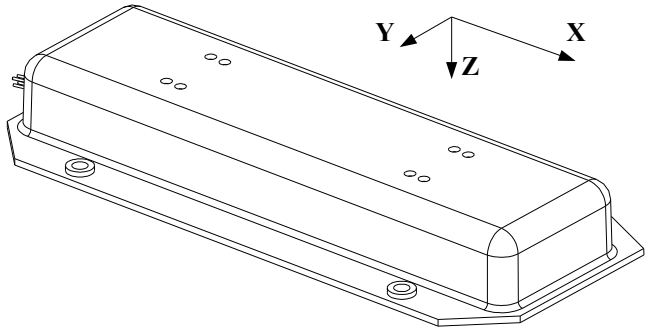
Compliance certifications for national regulations are attached to the document.

FCC:
This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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)]	$I_{standby}$	40	55	mA
Max .current consumption [2)]	I_{max}		350	mA
Reader Reset Threshold voltage	V_{Thres}	4,60	4,70	V_{DC}
Over voltage protection, Break down voltage	V_{Break}	6,45	7,14	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

The COBAS RFID reader has no internal fuses or any inrush current limitation. It is recommended to integrate an external fuse (500 mA, slow blow) into the power supply line to protect the reader and surrounding hardware against damage.

The circuitry is operates with an internally stabilized voltage for optimum and stable operation. A suppressor diode protects the COBAS RFID reader against over voltage. Specific data of the suppressor diode see appendix “1.5SMC6.8AT3-D”.

3.2 RFID data

Value	Symbol	Min	Max	Unit
RFID Frequency (typical)		13,56		MHz
Modulation degree according to ISO 15693		100%		%
Data transfer rate Tag <–> Reader according to ISO 15693	Data coding 1 out of 4 26,48 kBit/sec			
RFID Output power @ 50 Ω termination	P_{HF}		150	mW
Read distance [1)]	d_{Peak}	0	20	mm
Minimum distance between two labels (centre to centre of label) to avoid cross talking	d_{CC}	40		mm

Table 2: RFID measurement values

1) Measurement conditions: V = 5V, Transponder size = 20x10mm, Chip I-Code SLI
Transponder is converted to a label and placed on top of cassette, see also the following illustration
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

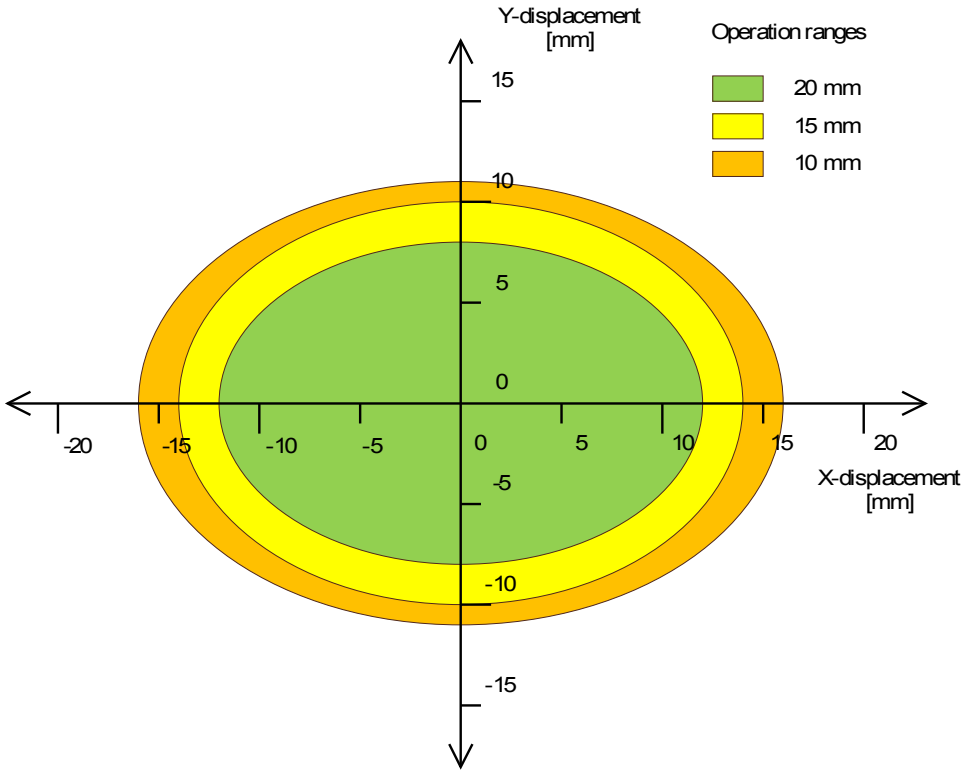


Diagram 1: Operation distance depending on label displacement

3.3 Optical sensors

Value	Symbol	Min	Max	Unit
Current consumption per Sensor channel	I_{Sensor}	28	30	mA
Wave length of sensor light	λ	629	661	nm
Response value "white" 1)	RV_{white}	80	200	Digits
Response value "black" 2)	RV_{black}	15	60	Digits
max. displacement in X-axis 3)	d_X		2	mm
max. displacement in Y-axis 3)	d_Y		3	mm
Settling time of sensors (measurement delay after LED is switched on)		5		ms

Table 3: Optical sensor values

1) Measurement conditions: V = 5V, distance between sensor and white paper = 15 mm
2) Measurement conditions: V = 5V, distance between sensor and black paper = 15 mm
3) Measurement conditions: V = 5V, distance between sensor and cassette = 15 mm

All values are measured with one channel switched on at one time. The following commands are used: WriteOutput and ReadAnalogInput according to the document "COBAS interface protocol v1.2"

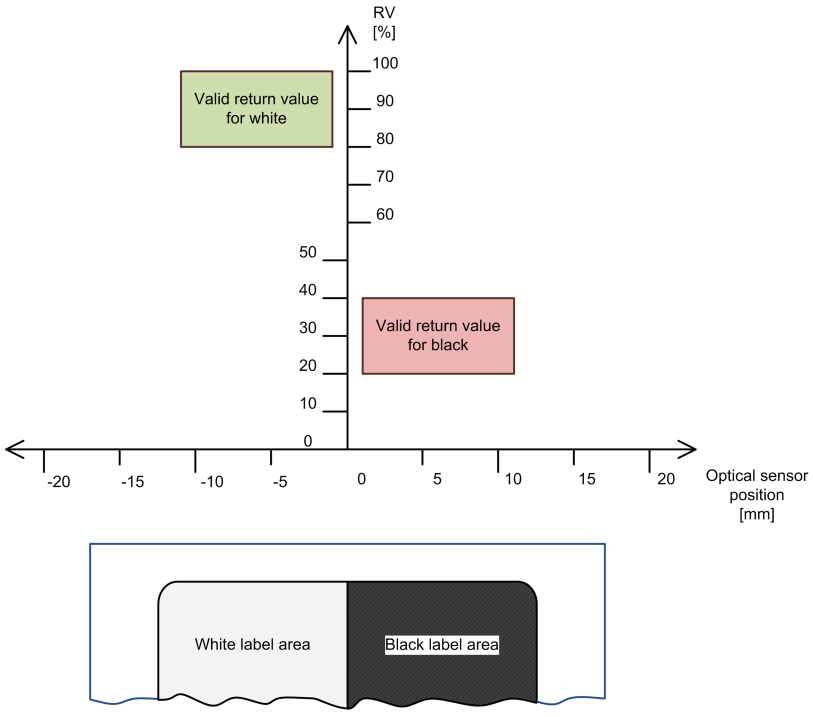


Diagram 2: Relative Return values of optical sensors depending on Y-position above label

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) [1)]		5	95	%
Requested protection against mechanical vibration in X/Y/Z direction at full operation [1,2)]			2,5	m/s^2
Normal operation after single shock in X/Y/Z direction [1,2)]			294	m/s^2
Housing protection class against intrusion of rigid particles and liquids (DIN EN 60529)			IP 30	

Table 4: Environmental conditions

1) Resistance against mechanical shock and humidity is depending on the reader housing and has to be verified
2) Exact specification of mechanical vibration and shock tests see below

Note: The COBAS RFID reader 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.

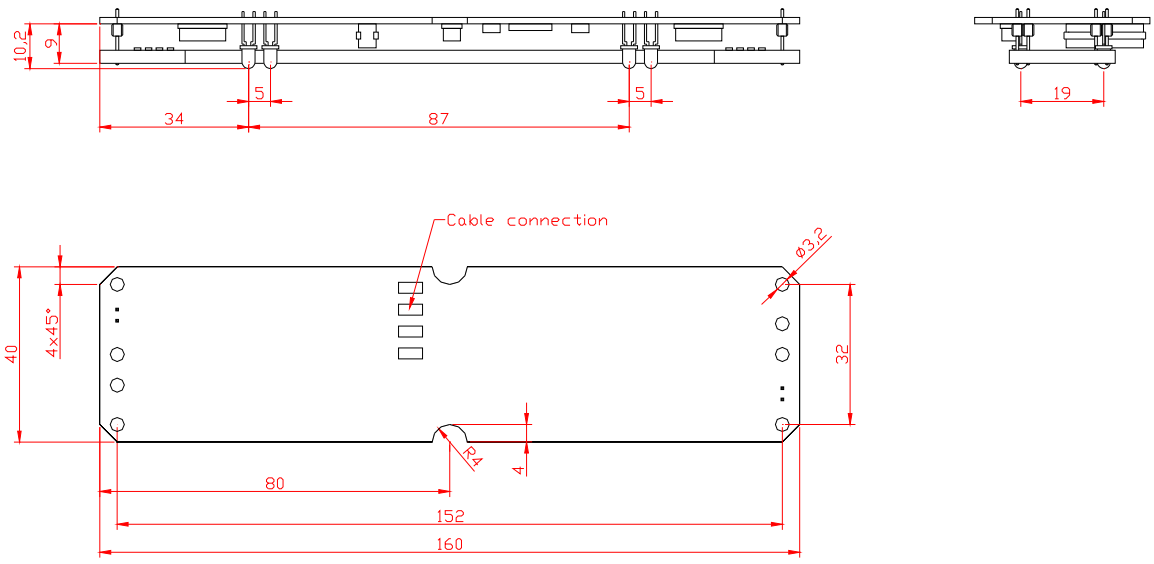
Because Hitachi has confidential internal standards the environmental tests are specified as follows:

- **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 RFID reader 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 RFID reader 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 RFID reader on during test

- **Damp heat, steady state, according to EN 60068-2-30**
  30°C exposure temperature
  5% relative humidity
  16h exposure time
  1 K/min temperature changing speed from RT to test temperature
  COBAS RFID reader on during test
- **Damp heat, steady state, according to EN 60068-2-30**
  30°C exposure temperature
  95% relative humidity, non condensing
  16h exposure time
  1 K/min temperature changing speed from RT to test temperature
  COBAS RFID reader 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 RFID reader 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 RFID reader 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 (±X, ±Y, ±Z)
  COBAS RFID reader 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 RFID reader without packaging
  COBAS RFID reader off during test

3.5 Dimensions

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



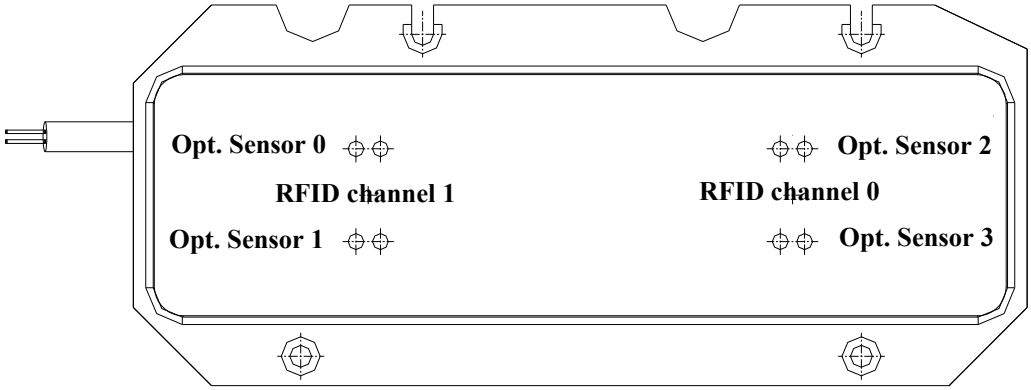
Drawing 3: Final assembly of COBAS RFID reader electronic

3.6 Dimensions of reader housing

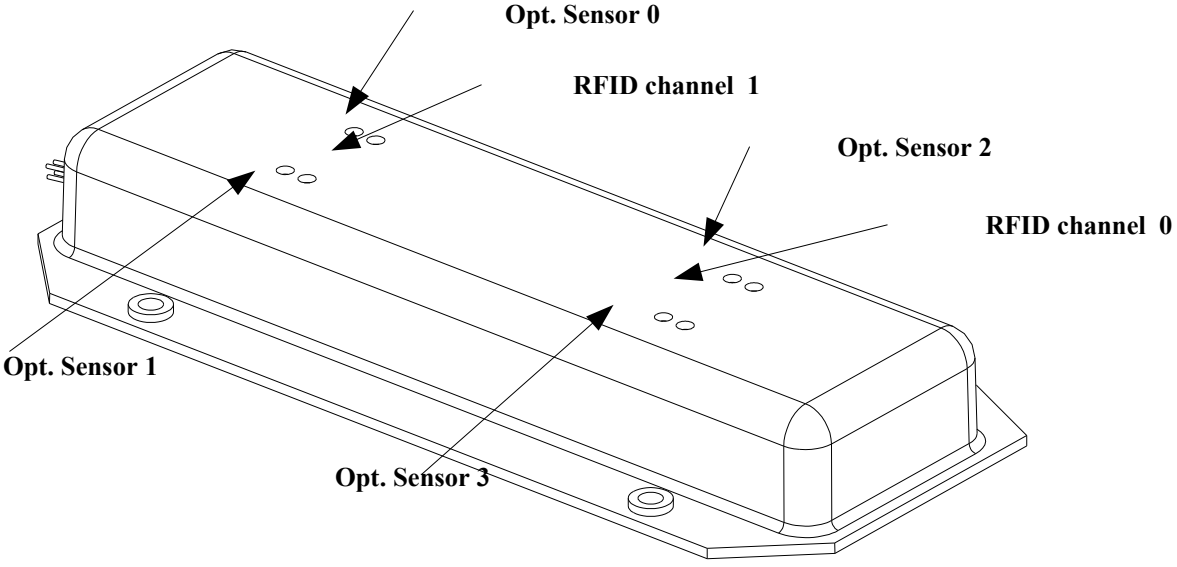
The reader housing is specified in drawing no. 7-50-1-1-2 (Document “Reader housing”) .

3.7 Channel positions

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



Drawing 4: Bottom view of COBAS RFID reader



Drawing 5: Side view of COBAS RFID reader

3.8 Connector

The COBAS RFID reader 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

Connector type: AMP D-2100, Product code 1318119

Drawing of cable: see attachment "Cable_v1.2.pdf"

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

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 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 RFID reader is defined in the document "COBAS Interface Protocol v1.2"

4 Packaging

Every COBAS RFID reader is packed into an ESD proof carton box shock protected with ESD save foam. Each carton box is labelled with a label containing, producer, factory number and serial number.

Zeichnung des Einzelkartons (maxsol)

5 Embargo list

The COBAS RFID reader contains electronic products made in the US which are classified as ECCN=EAR99.

Statement of the US Bureau of industry and Security (Copy of website http://www.bis.doc.gov/licensing/do_i_needaneccn.html, dated 23.07.2008)

However, EAR99 is a different type of classification. It serves as a "basket" designation for items that are covered by the EAR, but are not specified on the Commerce Control List. EAR99 items can be shipped without a license to most destinations under most circumstances. There are limitations on the use of EAR99. However, the majority of the commercial exports from the United States fall into this category.

The verification of all components is still ongoing!

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6 Installation notes

No special ESD prevention is required to assemble the COBAS RFID reader. 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 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. An optional heated glass plate could also be used for preventing water condensing at the optical sensor area. The glass type 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 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.

7 Possible interactions between the COBAS RFID reader and the host system

Several different failure modes could have an impact on the functionality of the host system. The COBAS RFID reader 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 a fuse (400mA, slow) into the power supply
Failure at the RS232 interface, like short or open wires	Standard RS232 interfaces are protected against short circuits or over voltage up to ±20V
Data failure inside the COBAS machine due to EMC / EMV	The reader will be qualified according to international standards. Shielding could also 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. Alternatively a reference label could be placed on the rotor to check the sensors for function before each reagent rotor scan.
Malfunction of the optical detection due to contamination by reactants	Periodical manual cleaning of the optical sensors by service personal or operators Alternatively a reference label could be placed on the rotor to check the sensors for function before each reagent rotor scan.
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.

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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.

Some components of the COBAS RFID reader might be discontinued without notice from their supplier. This might require a redesign and re-qualification of the electronic boards. etifix can not be liable for any delays in delivery in such cases. At announced product discontinuation etifix will inform the customer immediately about the announced last buy and last shipment dates for the certain product.

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.

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.

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

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9 Document revisions

Datum	Version	Status
27.11.07	0.1	1st 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 RFID readers (0-series production)

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Datum	Version	Status
	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