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cobas b 121 system

ASTM Interface Description

Roche Diagnostics

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Roche Diagnostics

Revision protocol

Imprint **cobas b** 121 system

In the course of 2005 the Roche OMNI C system will be relaunched under the Roche Diagnostics professional IVD user brand **cobas®**.

Systems with a serial number of 5001 or above are **cobas b** 121 systems.

Systems with a serial number up to 5000 are Roche OMNI C systems.

Use The **cobas b** 121 system is a modular analyzer for measuring blood gases, electrolytes, total hemoglobin, oxygen saturation and hematocrit in whole blood, serum, plasma, acetate and bicarbonate containing dialysis solutions, and QC materials.

CE Complies with the IVD directive 98/79/EC

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1. Introduction & General Information

The **cobas b** 121 system/Roche OMNI C system host communication is based upon the ASTM standard E1394, but is not a complete implementation of the standard. The actual implementation of the data transfer is described below.

Data can be transmitted via TCP/IP and the instruments built in UTP (unshielded twisted pair) network port as well as via serial connection over the COM 2 port. For a description of the low level protocols used, please see Low Level Protocols, page 21. For information on how to set up the connection, please see the APPENDIX, Connection Settings, page 31.

This description applies to software version 1.70.

This description applies to Roche OMNI C systems as well as to **cobas b** 121 systems; in case this description mentions one instrument type the topic also applies to the other. To identify the actual instrument type from the messages received, please refer to the serial number sent: Instruments with a serial number of 5001 or above are **cobas b** 121 systems, instruments with a serial number up to 5000 are Roche OMNI C systems.

2. Restricted Characters

None of the ten transmission control characters, the form effector control or the four device control characters may appear in message text. The following characters are not permitted to appear in the message text:

Illegal Message Text Characters				
<SOH>	<STX>	<ETX>	<EOT>	<ENQ>
<LF>	<ACK>	<DLE>	<NAK>	<SYN>
<ETB>	<DC1>	<DC2>	<DC3>	<DC4>

3. Message Structure

3.1 Explanation

Each message has a number of records. A *message* is a group of records that begins with a Header Record and ends with a Message Terminator Record. Each record has a number of fields. Each field is by default separated by the vertical bar | character (the actual definition of which character is used for field separation is done with the Header Record). Following is a description of the records and the fields within each record:

ID	Record Types		
H	Header Record	C	Comment Record
P	Patient Record	Q	Request Information Record
O	Test Order Record	M	Manufacturer Record
R	Result Record	L	Message Terminator Record

*Note: **The record type ID is** not **case sensitive, however, it is suggested to always use uppercase characters.***

3.1.1 Delimiters

Delimiters are ASCII characters used to separate fields within a record and to separate sub-components within fields. Below is a description of the delimiters and how they are commonly used:

Character	Name	Used as:
|	vertical bar	Field delimiter
\	backslash	Repeat delimiter
^	caret	Component delimiter
&	ampersand	Escape delimiter
<CR>	carriage return	Record delimiter

3.1.1.1 Field delimiter

Separates adjacent fields. |field|

3.1.1.2 Repeat delimiter

Must be defined in the message header and is used to separate various numbers of descriptors for the same field. I.E. A patient has two phone numbers. |555-5555\444-4444|

3.1.1.3 Component delimiter

Used to separate data elements within a field that has a hierarchical or qualifier nature. I.E. The components of a name field would be separated. |Sample^Josephine^X|

3.1.1.4 Escape delimiter

The escape delimiter is used to identify special case operations within a text field. For example, if text were supposed to be highlighted, the field would be |&H&DoctorsName&N&|. The &H& signifies the beginning of highlighting text and the &N& signifies the start of normal text.

The application of the escape delimiter is optional and may be ignored; however, all applications must accept the escape delimiter and use it to correctly parse fields within the record.

3.1.2 Null values

All fields are position dependent and are obtained by counting field delimiters by their position starting from the beginning of the record. This means if a field is null (no information available), the field delimiters must be included in the record. This ensures that the n^{th} field can be identified by counting n-1 delimiters. Trailing null fields do NOT need to be included. Delimiters are not needed after the last field containing data.

Null values may be sent for the following reasons:

- The value is not known.
- The sender knows the field is irrelevant to the receiving system.
- The value has not changed since the last transmission.

A field containing only a pair of double quotes "" should be treated by the receiving system as an instruction to delete any existing contents of that field.

Note: ***The receiving system may ignore any field it does not require. However, fields must always be transmitted in the order specified.***

3.2 Header Record

This record must always be the first record in a transmission. This record contains information about the sender and receiver, instruments and computer systems whose records are being exchanged. It also identifies the delimiter characters. The minimum information that must be sent in a Header record is:

H|\^&<CR>

The H corresponds to the record type, H=Header. The | (vertical bar) is used as the field delimiter. The \ (backslash) is the repeat delimiter. The ^ (carat) is the component delimiter. The & (ampersand) is the Escape delimiter. The <CR> is identified as a Carriage Return (ASCII decimal 13). The Carriage Return signifies the end of the record.

The entire header record consists of the following fields:

1|2|3|4|5|6|7|8|9|10|11|12|13|14<CR>

3.2.1 Example

H|\^&|||Roche^OMNI-C^1.60^1^1000||||||Meas|P|↵
1394-97|20050118133329<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always H
2	Delimiter definitions	Required, see the table in Delimiters. The first character is the field delimiter, the second is the repeat delimiter, the third is the component and the fourth is the escape character
3	Message Control ID	Not used by the instrument.
4	Access Password	Not used by the instrument.
5	Sender Name or ID	Manufacturer name, instrument type, software version, protocol version and serial number; separated by component delimiters.
6	Sender Street Address	Not used by the instrument.
7	Reserved Field	Not used by the instrument.
8	Sender Telephone #	Not used by the instrument.
9	Characteristic of Sender	Not used by the instrument.
10	Receiver ID	Not used by the instrument.
11	Comment or Special Instructions	Message type. Meas = measurement results, Qc = quality control results, = patient information query PQ = patient information query response.

Field #	Field Name	Comment
12	Processing ID	Indicates how message should be processed: P-Production, use standard processing
13	ASTM Version #	Required, currently 1394-97
14	Date and Time of message	Required Format=YYYYMMDDHHMMSS
<CR>	Carriage return	Required. Record Terminator

3.3 Patient Information Record

This record contains information about an individual patient. Patient information records are only actively used in a Measurement Report and a Patient Query. A QC Report contains a Patient Information Record without data due to ASTM standard compliance necessities.

In case of the answer to a patient query make sure not to send fields marked with (-); whether these fields are allowed is dependent on whether they have been explicitly enabled in Set-up – Displays & reports – Measurement data – Enter patient info.

The Patient Information record consists of the following fields:

1|2|3|4|5|6|7|8|9|10|11|12|13|14|15|16|17|18|19|20|21↵
|22|23|24|25|26|27|28|29|30|31|32|33|34|35<CR>

3.3.1 Example

P|1|Pract Pat ID|Pat ID||Last name^First name^M||19691202|F|||||||↵
156^cm|45.0^kg||||||00000000000000/00000000000000||||||||||<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always P
2	Sequence#	Required, sequentially generated number identifying the number of each record.

Field #	Field Name	Comment
3	Practice assigned Patient ID	A unique ID assigned and used by the practice to identify the patient and his/her results. Used by practice to identify the results returned by the tester (lab).
4	Laboratory Patient ID	Laboratory assigned ID. This is a unique processing number generated by the lab, the LIS, or the HIS (bar code number).
5	Patient ID No. 3	(-) Used for transmitting the patient's insurance number.
6	Patient Name	This field is the patients name in the following format: Last^First^Middle. Each component separated by the component delimiter.
7	Mother's Maiden Name	(-) Generic text as entered at the instrument.
8	Date of Birth	Format=YYYYMMDD
9	Patient Sex	Format M (male), F (female), or U (unknown), null if not entered.
10	Patient Race	(-) Transmits patient skin colour.
11	Patient Address	(-) Generic text as entered at the instrument.
12	Reserved	Not used by the instrument.
13	Patient Telephone #	(-) Generic text as entered at the instrument.
14	Attending Physician	ID of the attending physician.
15	Special field 1	Not used by the instrument.

Field #	Field Name	Comment
16	Special field 2	Not used by the instrument.
17	Patient Height	Format value^unit.
18	Patient Weight	Format value^unit.
19	Known or suspected diagnosis	(-) Generic text as entered at the instrument.
20	Patient active medications	(-) Generic text as entered at the instrument.
21	Patient diet	(-) Generic text as entered at the instrument.
22	Practice field 1	Not used by the instrument.
23	Practice field 2	Not used by the instrument.
24	Admission and discharge data and time	(-) Format= YYYYMMDDHHMMSS\ YYYYMMDDHHMMSS All zeros if no date entered
25	Admission status	(-) Generic text as entered at the instrument.
26	Location	(-) Generic text as entered at the instrument.
27	Diagnostic Code	(-) Generic text as entered at the instrument.
28	Alternative Diagnostic Code	Not used by the instrument.
29	Patient Religion	(-) Generic text as entered at the instrument.
30	Marital Status	(-) Generic text as entered at the instrument.
31	Isolation Status	(-) Generic text as entered at the instrument.

Field #	Field Name	Comment
32	Language	(-) Generic text as entered at the instrument.
33	Hospital Service	(-) Generic text as entered at the instrument.
34	Hospital Institution	(-) Generic text as entered at the instrument.
35	Dosage Category	(-) Generic text as entered at the instrument.
<CR>	Carriage Return	Required. Record terminator

3.4 Test Order Record

The order record defines the particular type of tests run or performed for each specimen. The order record for the **cobas b** 121 system/Roche OMNI C system only is transmitted to the host computer as part of the measurement report.

The Test Order record consists of the following fields:

1|2|3|4|5|6|7|8|9|10|11|12|13|14|15|16|17|18|19|20|21|22|23|24|25|26|27|28|29|30|31<CR>

3.4.1 Example

O|1|Specimen ID|MEASUREMENT^56|||||||Operator ID|||||↵
blood^arterial^umbilical<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always O
2	Sequence#	Required, sequential number
3	Specimen ID	Account or bar code number for patient result messages, always 0 for QC messages
4	Instrument Specimen ID	Order ID^Sample number.

Field #	Field Name	Comment
5	Universal Test ID	Not used by the instrument.
6	Priority	Not used by the instrument.
7	Requested /Order Date and Time	Not used by the instrument.
8	Specimen collection date and time	Not used by the instrument.
9	Collection end time	Not used by the instrument.
10	Collection volume	Not used by the instrument.
11	Collector ID	Operator ID.
12	Action code	Not used by the instrument.
13	Danger code	Generic text as entered at the instrument.
14	Relevant clinical information	Generic text as entered at the instrument (Clinic Info).
15	Date/Time specimen received	Not used by the instrument.
16	Specimen descriptor	Includes the specimen & blood type as well as the source (puncture site), separated by component delimiters.
17	Ordering Physician	Not used by the instrument.

Field #	Field Name	Comment
18	Physician's Telephone Number	Not used by the instrument.
19	User field 1	Not used by the instrument.
20	User field 2	Not used by the instrument.
21	Laboratory Field 1	Not used by the instrument.
22	Laboratory Field 2	Not used by the instrument.
23	Date/Time Results Reported or Last Modified	Not used by the instrument.
24	Instrument Charge to Computer System	Not used by the instrument.
25	Instrument Section ID	Not used by the instrument.
26	Report Types	Not used by the instrument.
27	Reserved Field	Not used by the instrument.
28	Location or Ward of Specimen Collected	Not used by the instrument.
29	Nosocomial Infection Flag	Not used by the instrument.
30	Specimen Service	Not used by the instrument.

Field #	Field Name	Comment
31	Specimen Institution	Not used by the instrument.
<CR>	Carriage Return	Required. Record Terminator

3.5 Result Record

The result record is used to send actual patient results that were performed on an instrument. The Result record consists of the following fields:

1|2|3|4|5|6|7|8|9|10|11|12|13|14|<CR>

3.5.1 Example

R|1|^ ^ ^pH^ ^ ^M^1|-||7.350^7.450^reference\↵
7.200^7.600^critical|A||X||Operator ID||20050118132926|<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always R.
2	Sequence#	Required, sequentially generated number identifying the number of each record.
3	Universal Test ID	^ ^ ^Test name^ ^ ^how value was derived (M-Measured, C-Calculated, I-Input)^Result ID (see tables in APPENDIX)
4	Data measurement or value	Result value (Cut-off index not used)
5	Units	Same as selected for instrument display.
6	Reference ranges	Reference range of the analyte. Format is lower limit^upper limit^limit name. Multiple ranges are separated by repeat delimiters.

Field #	Field Name	Comment
7	Result Abnormal Flags	Dilution information, Errors, etc. Characters identifying these flags are: N Normal A Abnormal L Reference low H Reference high LL Below panic HH Above panic
8	Nature of abnormality testing	A, S, N or empty.
9	Result Status	Status of the result: F Final X Results cannot be done
10	Date of Change in Instrument Normative Values	Not used by instrument.
11	Operator Identification	Identifies operator who performed the test (instrument operator). *Note: Only transmitted in the first result record.*
12	Date/Time Test Started	Not used by the instrument.
13	Date/Time Test Completed	The date and time the instrument completed the test. Format=YYYYMMDDHHMMSS *Note: Only transmitted in the first result record.*
14	Instrument Identification	Not used by the instrument.
<CR>	Carriage Return	Required. Record Terminator

3.6 Request Information Record

The Request Information Record is used for querying a host system for patient demographics. The response message to an information request has to consist of a Header Record, a Patient Information Record and a Message Terminator Record. The Message Terminator Record in this case has to end with one of the query response codes. The Request Information Record consists of the following fields:

1|2|3|4|5|6|7|8|9|10|11|12|13<CR>

3.6.1 Example

Q|1|Pat ID|||||||||D<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always is Q.
2	Sequence#	Required, sequentially generated number identifying the number of each record.
3	Starting Range ID Number	Laboratory Patient ID, entered during measurement.
4	Ending Range ID Number	Not used by the instrument.
5	Universal Test ID	Not used by the instrument.
6	Nature of Request Time Limits	Not used by the instrument.
7	Beginning Request Results Date and Time	Not used by the instrument.
8	Ending Request Results Date and Time	Not used by the instrument.
9	Requesting Physician Name	Not used by the instrument.

Field #	Field Name	Comment
10	Requesting Physician Telephone Number	Not used by the instrument.
11	User Field No. 1	Not used by the instrument.
12	User Field No. 2	Not used by the instrument.
13	Request Information Status Codes	D – Requesting demographics only
<CR>	Carriage Return	Required. Record Terminator

3.7 Comment Record

Comment records may be inserted anywhere except after the message terminator record. Each comment record applies to the first non-comment record preceding it. Comment records are currently inserted after the order record (comment entered by the operator) and after result records in case a correlation has been applied to this result. The Comment record consists of the following fields:

1|2|3|4|5<CR>

3.7.1 Example

C|1|I|The Remark|G<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always is C.
2	Sequence#	Required, sequentially generated number identifying the number of each record.
3	Comment Source	I Clinical Instrument
4	Comment Text	For comment codes used, the format is code^comment.

Field #	Field Name	Comment
5	Comment Type	Used to qualify comment records. G Generic/Free Text I Instrument flag comment
<CR>	Carriage Return	Required. Record Terminator

3.8 Message Terminator Record

This is the last record in the message. A header record may be transmitted after this record to signify the start of another message. The Message Terminator record consists of the following:

1|2|3<CR>

3.8.1 Example

L|1|N<CR>

Field #	Field Name	Comment
1	Record Type ID	Required, always is L.
2	Sequence#	Required, sequentially generated number identifying the number of each record.
3	Termination code	N normal termination T sender aborted E unknown system error Q error in last request for information I no information available from last query F last request for information processed
<CR>	Carriage Return	Required. Record Terminator

3.9 Manufacturer Information Record

For the **cobas b** 121 system/Roche OMNI C system this record is used for transmitting calibration and maintenance data only and will only be transmitted, when "additional data (DC)" is activated.

The Manufacturer Information record will consist of the following:

1|2|3<CR>

3.9.1 Example

M|1|<CR>

Field #	Field Name	Comment
1	Record Type	Required, always is M.
2	Sequence#	Required, sequentially generated number identifying the number of each record.
3	Any number of fields	Calibration or maintenance information.
<CR>	Carriage Return	Required. Record Terminator

3.10 Note

For all records, fields up to and including the last field with data needs to be transmitted. Fields not used at the end of the record may be truncated.

4. Low Level Protocols

4.1 TCP/IP Connection

For TCP/IP connection, no specific low level protocol is used. Correct and complete communication is ensured by the TCP/IP protocol itself.

4.2 Serial Connection

For serial communication, the low level protocol as specified with ASTM E1381 is used. A detailed description of the
cobas b 121 system/Roche OMNI C system implementation can be found in the following.

4.2.1 Control Characters

Control characters that are used for ASTM communications:

ASCII	Decimal	Hex	Control char.	Comment
<STX>	2	0x2	^B	**S**tart of **T**e**X**t
<ETX>	3	0x3	^C	**E**nd of **T**e**X**t
<EOT>	4	0x4	^D	**E**nd **O**f **T**ransmission
<ENQ>	5	0x5	^E	**ENQ**uiry
<ACK>	6	0x6	^F	**ACK**nowledge
<LF>	10	0xA	^J	**L**ine **F**eed
<CR>	13	0xD	^M	**C**arriage **R**eturn
<NAK>	21	0x15	^U	**N**egative **A**c**K**nowledge
<ETB>	23	0x17	^W	**E**nd of **T**rans. **B**lock

4.2.2 Communication Phases

There are 3 distinct phases to each communication session: The Establishment phase, the Transfer phase and the Termination phase. Each of these phases will be discussed in the following paragraphs.

4.2.2.1 Establishment Phase

When the instrument is ready to send data, it transmits an <ENQ> character. After the <ENQ> is sent, the instrument waits for a maximum of 15 seconds for a response from the host. If there is no response from the host within 15 seconds, the <ENQ> is resent. This loop is repeated for a maximum of six times. If there is no response after these six retries, communication is aborted.

Sender	Recipient
<ENQ>	
	<ACK> or <NAK>

If an <ACK> character is received from the host, the establishment phase is successful, and the transfer phase follows. If a <NAK> character is received from the host, the instrument waits a minimum of 10 seconds, then resends the <ENQ> after receipt of the <NAK> and repeats this loop until an ACK is received. If the host continues to respond with <NAK> after six retries, communication is aborted.

This ends the Establishment phase of the communication session.

4.2.2.2 Transfer Phase

During the transfer phase the sender transmits messages to the receiver. The transfer continues until all messages have been sent.

Sender>

<STX>	FN	data	<ETB> or <ETX>	CS	<CR><LF>

Receiver<

<ACK>

Explanation of fields:

<STX>	Start of text, ASCII decimal 2. This control character identifies the starting point of the data that is being sent from the analyzer. This character must accompany all data transmissions.
FN	Frame number. A single digit field distinguishing between new and re-transmitted frames. Legal characters are ASCII '0' to '7'. The frame number must start at 1 with the first frame of the transfer phase. The frame number is incremented by one for every new frame transmitted. After '7', the frame number rolls over to '0', and continues in this fashion.
Data	Data is one of the records described in the Message Structure section, starting page 5.
<ETB> Or <ETX>	The <ETB> character stands for End of Transmission Block and is only sent when there are multiple frames. When a message contains over 240 characters it is broken into two or more frames. The intermediate frame must be terminated with an <ETB> (end of transmission block), CS (checksum), <CR> (carriage return) and <LF> (line feed). The final frame is terminated with an <ETX> (end of text), CS (checksum), <CR> (carriage return) and <LF> (line feed). The frame structure is illustrated below. <STX> FN data <ETB> CS <CR><LF> ⇐ Intermediate frame(s) <STX> FN data <ETX> CS <CR><LF> ⇐ End frame
CS	The CS (checksum) is used for checking data integrity. The checksum is computed by adding the binary values of the character, keeping the lowest significant 8 bits of the result. The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The calculation of the checksum does not include the <STX>, the checksum characters, or the trailing <CR> and <LF> (the <ETX>/<ETB> is included in the calculation). The checksum is transmitted as two ASCII characters (hexadecimal representation). The two characters are transmitted as the checksum, with the most significant character first (C1). For example, a checksum of 122 can be represented as 0x7A (0x stands for hexadecimal). The checksum is transmitted as the ASCII character ‘7’ followed by the character ‘A’.
<CR> <LF>	The <CR> (carriage return) and <LF> (line feed) combination is used as the end termination characters of the message text.

4.2.2.2.1 Acknowledgements

After each frame is sent, the sender waits up to 15 seconds for a reply. The receiver shall transmit one of three replies:

<ACK> (Decimal 06)

The <ACK> reply signifies the last frame was received and processed successfully and it is OK to send another frame. The sender increments the frame number and either sends a new frame or terminates the transmission (see termination phase).

<NAK> (Decimal 21)

The <NAK> reply signifies the last frame was not received successfully and the receiver is prepared to receive it again. The sender will retransmit it with the same frame number.

<EOT> (Decimal 04)

The <EOT> reply signifies the last frame was received successfully and the receiver is prepared to receive another frame, but requests the sender to stop transmitting data. See interrupts below.

4.2.2.2.2 Interrupts

During the transfer phase, if the receiver responds to a frame with an <EOT> in place of an <ACK>, the sender must interpret this as an interrupt request. The <EOT> signifies the last frame was successful, but the receiver is requesting the sender to stop transmitting. If the sender chooses to ignore the <EOT>, the receiver must resend the <EOT> for the interrupt to remain valid. If the sender chooses to honour the interrupt, the sender must enter the termination phase (See termination phase below). The sender must not enter the establishment phase for at least 15 seconds or until the receiver has finished a message cycle (establishment, transfer, termination).

4.2.2.3 Termination Phase

The termination phase returns the communication link to the clear or neutral state. The sender notifies the receiver that all messages have been sent.

Sender	Recipient
<EOT>	
	No response

The termination phase is a sequence of conditions that will cause communication between the devices to cease. The termination phase is entered when the sender has no more data to transmit. Termination is accomplished by transmitting an <EOT>. When the <EOT> is sent, no acknowledgement is needed, do not expect an <ACK>. The receiver, upon receiving <EOT>, considers the communication to have ended and sends no further data or acknowledgements.

4.2.3 Error Recovery

A receiver checks every frame for valid data. To check data, the receiver calculates the checksum on the received data and compares this calculated checksum to the checksum that was transmitted by the sender and sent with the data stream. If the checksums match, the data is valid. If the checksums do not match, the data is not valid and the receiver must send a <NAK>. Upon receiving the <NAK>, the sender re-transmits the last frame with the same frame number.

A frame should be rejected for the following errors:

- Any character errors are detected (parity error, framing error, etc.).
- The calculated frame checksum does not match the checksum in the received frame.
- The frame number is not one higher than the last accepted frame.

Upon receiving a <NAK>, or any character except <ACK> or <EOT>, the sender increments a re-transmit counter and re-transmits the same frame (with the same frame number). If the counter shows the frame was not accepted after six times, the sender must abort the message and proceed immediately to the termination phase.

4.2.4 Time-outs

If the reply after sending an <ENQ> is not received within 15 seconds, the sender enters the termination phase.

If the receiver detects contention and no <ENQ> is received within 20 seconds, the receiver regards the data link to be in the neutral state.

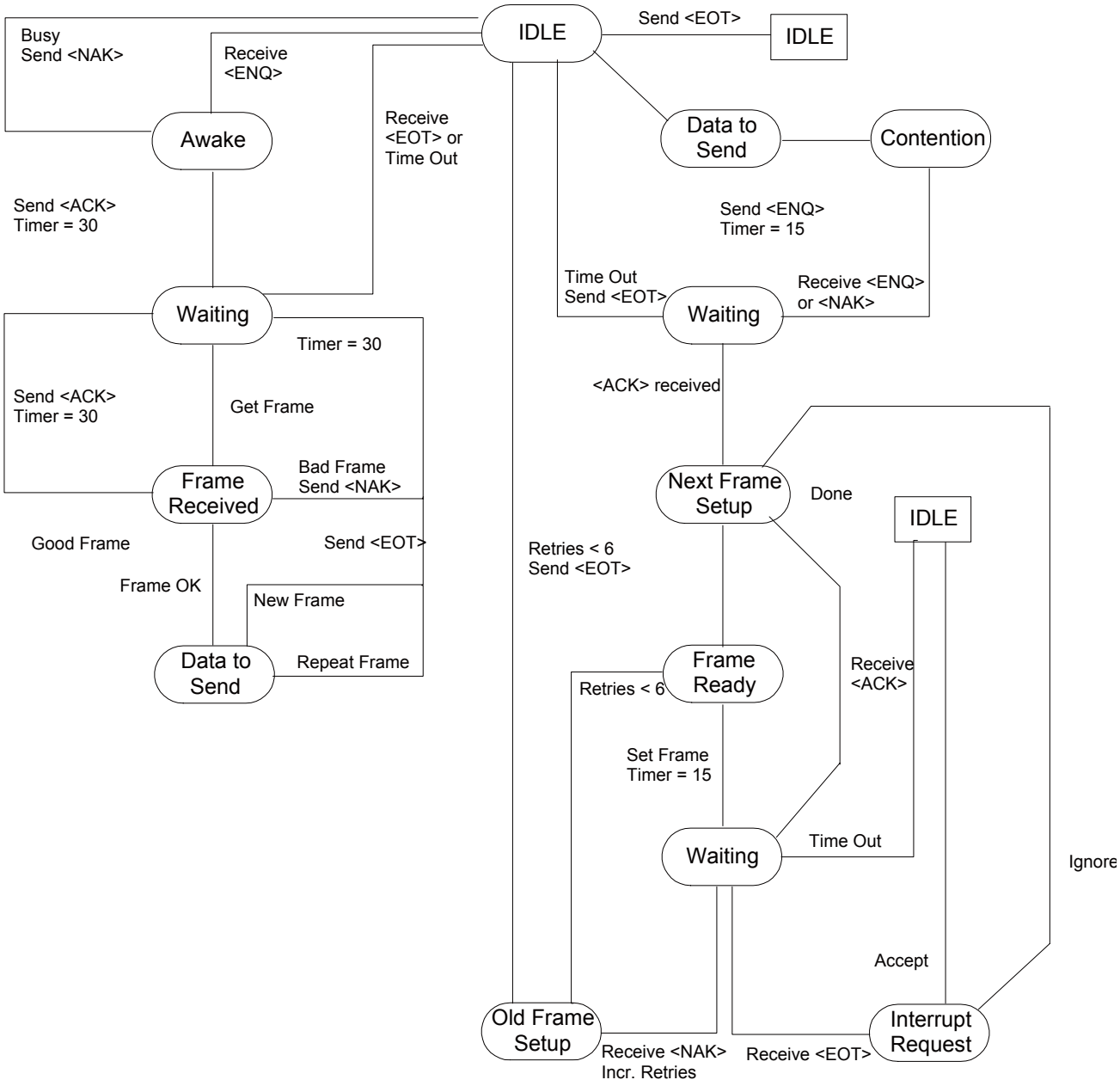
If the sender receives no reply within 15 seconds after transmitting the last character of a frame, it aborts the message by entering the termination phase.

During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or an <EOT> is not received within 30 seconds, the receiver discards the incomplete message and regards the line to be in the neutral state.

The receiver can delay its reply for up to 15 seconds. Longer delays cause the sender to abort the message.

4.2.5 State Diagram

Receiving Device **Sending Device**



5. Data Examples

5.1 Measurement Report

```
H|\^&|||Roche^OMNI-C^1.60^1^1000||||||Meas|P|1394-97|20050118133329
P|1|Pract Pat ID|Pat ID||Last name^First
name^M||19691202|F|||||||156^cm|45.0^kg|||||00000000000000/00000000000000||||||||||
O|1|Specimen ID|MEASUREMENT^56|||||||Operator ID|||||blood^arterial^umbilical
C|1|I||G
R|1|^^^pH^^^M^1|-||7.350^7.450^reference\7.200^7.600^critical|A||X||Operator ID||20050118132926|
C|1|I|Corrected|G
R|2|^^^PCO2^^^M^4|-|mmHg|35.0^45.0^reference\20.0^60.0^critical|A||X|||||
C|1|I|Corrected|G
R|3|^^^PO2^^^M^3|156.6|mmHg|80.0^100.0^reference\60.0^800.0^critical|H||F|||||
C|1|I|Corrected|G
R|4|^^^Na^^^M^6|-|mmol/L|135.0^148.0^reference\125.0^160.0^critical|A||X|||||
C|1|I|Corrected|G
R|5|^^^K^^^M^7|18.91|mmol/L|3.50^4.50^reference\2.80^6.00^critical|HH||F|||||
C|1|I|Corrected|G
R|6|^^^Cl^^^M^9|-|mmol/L|98.0^107.0^reference\80.0^115.0^critical|A||X|||||
C|1|I|Corrected|G
R|7|^^^iCa^^^M^8|-|mmol/L|1.120^1.320^reference\1.050^1.500^critical|A||X|||||
C|1|I|Corrected|G
R|8|^^^tHb^^^M^10|-|g/dL|12.0^15.0^reference\8.0^23.0^critical|A||X|||||
C|1|I|Corrected|G
R|9|^^^SO2^^^M^11|-|%|75.0^99.0^reference\60.0^100.0^critical|A||X|||||
C|1|I|Corrected|G
R|10|^^^Hct^^^M^5|-|%|35.0^50.0^reference\25.0^65.0^critical|A||X|||||
C|1|I|Corrected|G
R|11|^^^Temperature^^^I^155|37.0|°C||||F|||||
R|12|^^^Baro^^^M^31|724.1|mmHg||||F|||||
R|13|^^^cHCO3^^^C^51|-|mmol/L||A||X|||||
R|14|^^^ctCO2(P)^^^C^52|-|mmol/L||A||X|||||
R|15|^^^SO2(c)^^^C^58|-|%||A||X|||||
R|16|^^^BE^^^C^53|-|mmol/L||A||X|||||
R|17|^^^BEecf^^^C^55|-|mmol/L||A||X|||||
R|18|^^^BB^^^C^56|-|mmol/L||A||X|||||
R|19|^^^ctO2^^^C^60|-|Vol%||A||X|||||
R|20|^^^ctCO2(B)^^^C^61|-|mmol/L||A||X|||||
R|21|^^^pHst^^^C^62|-|||A||X|||||
R|22|^^^cHCO3st^^^C^63|-|mmol/L||A||X|||||
R|23|^^^HbI^^^C^200|-|||A||X|||||
R|24|^^^PAO2^^^C^64|-|mmHg||A||X|||||
R|25|^^^AaDO2^^^C^65|-|mmHg||A||X|||||
R|26|^^^a/AO2^^^C^66|-|%||A||X|||||
R|27|^^^avDO2^^^C^67|-|%||A||X|||||
R|28|^^^RI^^^C^68|-|%||A||X|||||
R|29|^^^niCa^^^C^70|-|mmol/L||A||X|||||
R|30|^^^AG^^^C^71|-|mmol/L||A||X|||||
R|31|^^^pHt^^^C^72|-|||A||X|||||
R|32|^^^H+t^^^C^73|-|nmol/L||A||X|||||
R|33|^^^PCO2t^^^C^74|-|mmHg||A||X|||||
```

```
R|34|^^^PO2t^^^C^75|156.6|mmHg||||F|||||
R|35|^^^PAO2t^^^C^76|-|mmHg||A||X|||||
R|36|^^^AaDO2t^^^C^77|-|mmHg||A||X|||||
R|37|^^^a/AO2t^^^C^78|-|%||A||X|||||
R|38|^^^RIt^^^C^79|-|%||A||X|||||
R|39|^^^Hct(c)^^^C^80|-|%||A||X|||||
R|40|^^^MCHC^^^C^81|-|g/dL||A||X|||||
R|41|^^^BO2^^^C^84|-|||A||X|||||
R|42|^^^BEact^^^C^54|-|mmol/L||A||X|||||
R|43|^^^Osm^^^C^82|-|mOsm/kg||A||X|||||
R|44|^^^OER^^^C^83|-|%||A||X|||||
R|45|^^^Qs/Qt^^^C^69|-|%||A||X|||||
R|46|^^^Qt^^^C^86|-|%||A||X|||||
R|47|^^^P/F^^^C^88|745.7|mmHg||||F|||||
R|48|^^^ALLEN test^^^I^152|ErrTxt[1641]|||||F|||||
R|49|^^^A/F^^^I^154|adult|||||F|||||
R|50|^^^P50^^^I^156|-|mmHg||A||X|||||
R|51|^^^R^^^I^157|0.840|||||F|||||
R|52|^^^FIO2^^^I^158|0.210|||||F|||||
L|1|N
```

5.2 QC Report

```
H|\^&|||Roche^OMNI-C^1.60^1^1000||||||Qc|P|1394-97|20050118132609
O|1|479774398|QC^55||||||||||COMBITROL TS^1^21741502^aqueous
C|1|I||G
R|1|^^^Na^^^M^600|-|mmol/L|120.0^128.0|A||F||||20050104131059|
R|2|^^^Cl^^^M^601|-|mmol/L|83.0^91.0|A||F|||||
R|3|^^^pH^^^M^602|-||7.150^7.210|A||F|||||
R|4|^^^iCa^^^M^603|-|mmol/L|1.400^1.700|A||F|||||
R|5|^^^K^^^M^604|-|mmol/L|2.80^3.20|A||F|||||
R|6|^^^PO2^^^M^605|135.5|mmHg|45.0^69.0|H||F|||||
R|7|^^^PCO2^^^M^606|-|mmHg|61.0^69.0|A||F|||||
R|8|^^^tHb^^^M^607|14.2|g/dL|17.4^19.6|L||F|||||
R|9|^^^SO2^^^M^608|94.7|%|98.0^102.0|L||F|||||
R|10|^^^Hct^^^M^609|43.5|%|51.0^61.0|L||F|||||
```

5.3 Patient Query

```
H|\^&|||Roche^OMNI-C^1.60^1^1000|||||||P|1394-97|20050118133359
Q|1|Pat ID|||||||||D
L|1|N
```

5.4 Calibration Report

```
H|\^&|||Roche^OMNI-C^1.60^1^1000||||||SR^REAL|P|1394-97|20050118132556
M|1|SR^RO^OC^1|308^PO2^1P Pot|-|mV|330^250^550|A^Fill Ref 1565||20050117181344
M|2|SR^RO^OC^1|310^PO2^Slp Pot|2.58|mV|2^-10^15|N
M|3|SR^RO^OC^1|312^PCO2^1P Pot|-|mV|-1000^-1300^2000|A^Fill Ref 1565
M|4|SR^RO^OC^1|314^PCO2^Slp Pot|-|mV|-143^-160^-110|A^1P was nOk 2004
M|5|SR^RO^OC^1|320^Na^1P Pot|-|mV|950^-1700^2300|A^Fill Ref 1565
M|6|SR^RO^OC^1|322^Na^Slp Pot|-|mV|130^110^140|A^1P was nOk 2004
M|7|SR^RO^OC^1|332^Cl^1P Pot|-|mV|700^-2300^1700|A^Fill Ref 1565
M|8|SR^RO^OC^1|334^Cl^Slp Pot|-|mV|-108^-120^-90|A^1P was nOk 2004
M|9|SR^RO^OC^1|324^K^1P Pot|-|mV|550^-1700^2100|A^Fill Ref 1565
M|10|SR^RO^OC^1|326^K^Slp Pot|-|mV|130^110^140|A^1P was nOk 2004
M|11|SR^RO^OC^1|328^Ca^1P Pot|-|mV|500^-2000^2200|A^Fill Ref 1565
M|12|SR^RO^OC^1|330^Ca^Slp Pot|-|mV|-87^-95^-65|A^1P was nOk 2004
M|13|SR^RO^OC^1|316^pH^1P Pot|-|mV|500^-2100^1600|A^Fill Ref 1565
M|14|SR^RO^OC^1|318^pH^Slp Pot|-|mV|-305^-340^-250|A^1P was nOk 2004
M|15|SR^RO^OC^1|401^ORDERBITS|2P cal. incl. O2|||N
M|16|SR^RO^OC^1|402^Baro|736.8|mmHg||N
M|17|SR^RO^OC^1|409^DateTime|20050117181344|||N
L|1|N
```

5.5 Maintenance Report

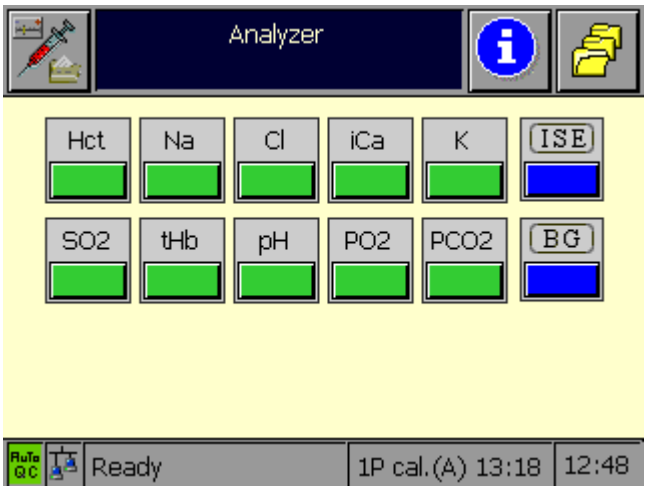
```
H|\^&|||Roche^OMNI-C^1.60^1^1000||||||LSU^U12|P|1394-97|20050118132435
M|1|EQU^RO^OC^1|Instrument|20050118132435|OP||N
M|2|EQP^RO^OC^1|1^LOG||20050118132435||55^1^604^1^ ^
L|1|N
```

6. APPENDIX

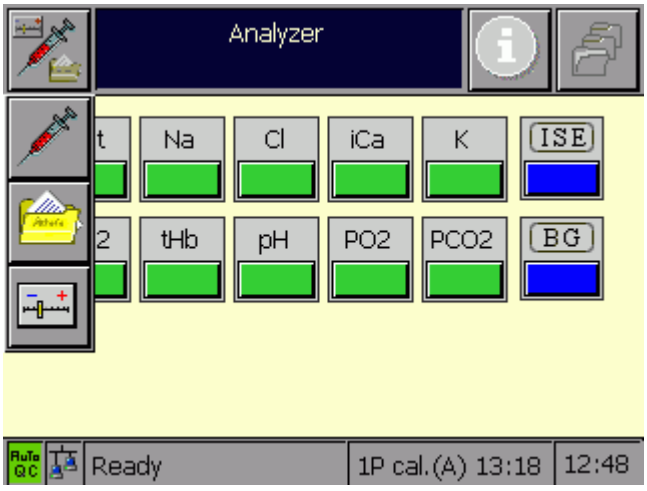
6.1 Connection Settings

6.1.1 General

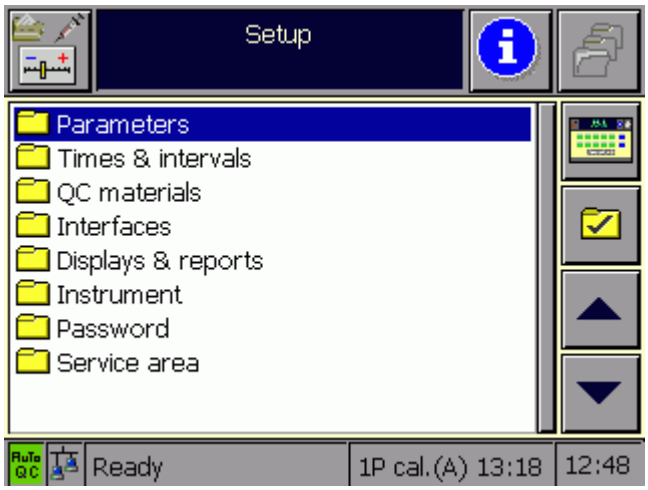
The **cobas b** 121 system/Roche OMNI C system connection settings are done in the Interface section of the setup mode. To get there, please follow the steps listed below:



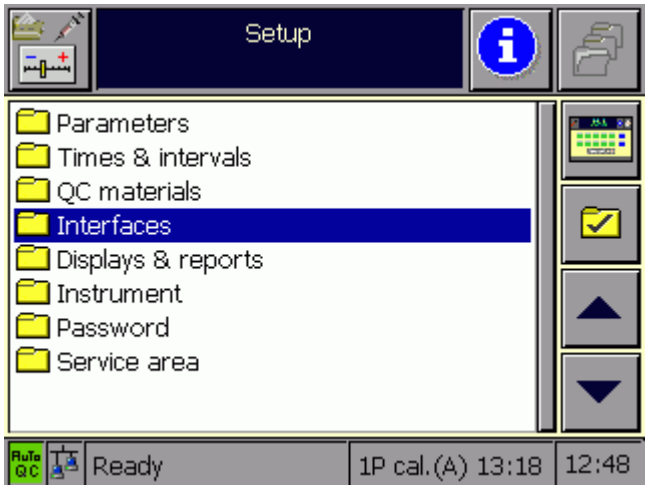
Press the **task switch button** in the upper left corner of the screen.



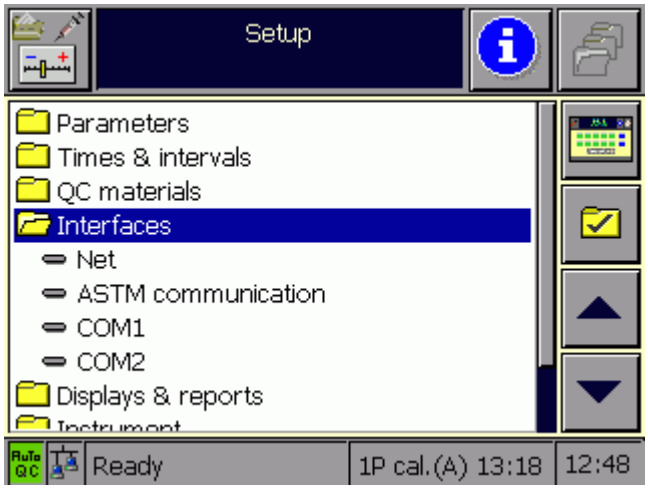
Select the **setup** mode (the lowest icon).



Select **Interfaces** either by using the arrow buttons or by directly pressing the line.



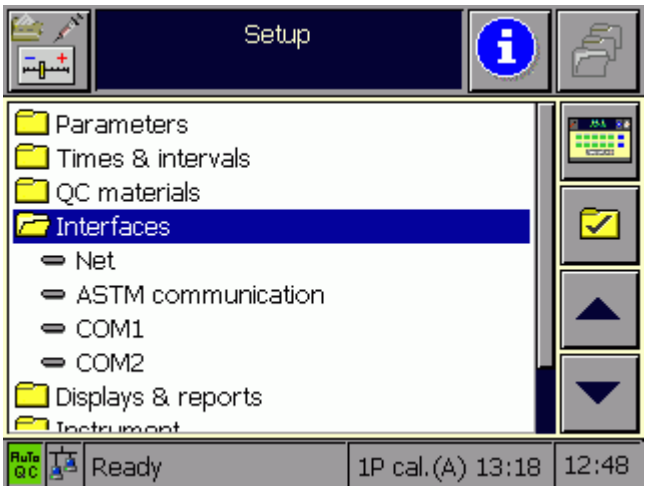
Press the **activation** button above the arrow buttons.



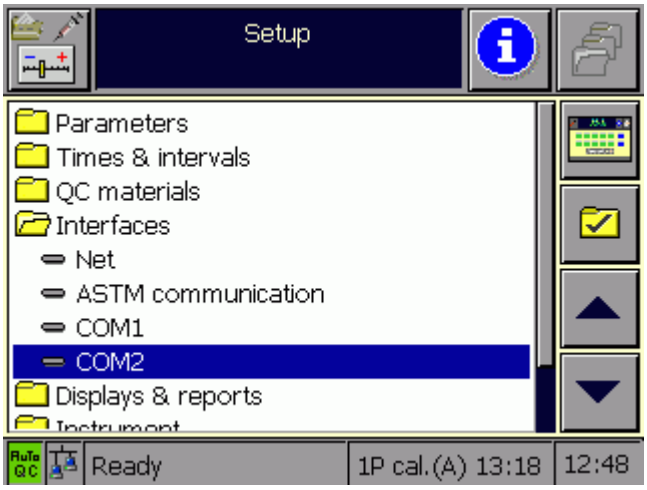
To proceed, please see either Serial Connection or TCP/IP Connection.

6.1.2 Serial Connection

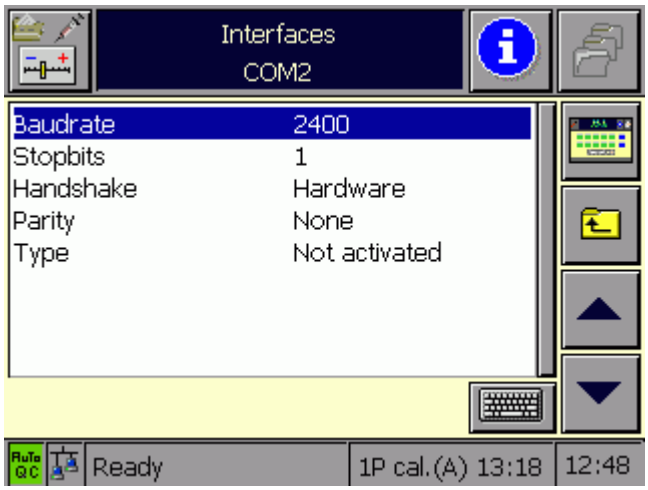
Make sure, that the instrument's COM 2 interface (on the instrument's rear) is connected to the host or host device using a 9 pin null modem cable. The COM 1 interface is reserved for other purposes and can not be used for ASTM communication.



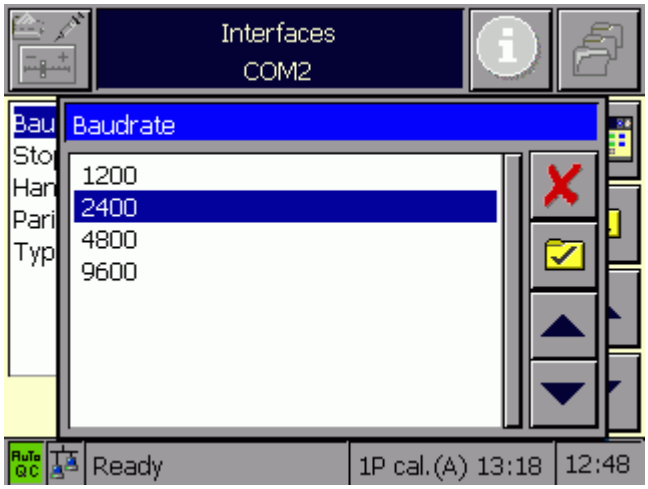
Select **COM2**.



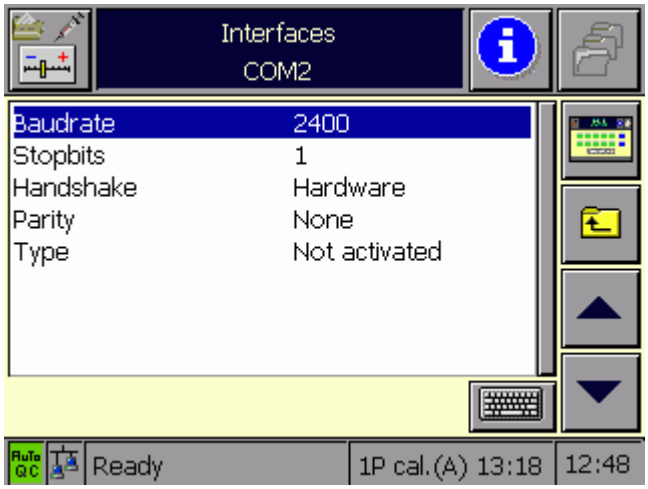
Press the **activation** button (above the arrow buttons).



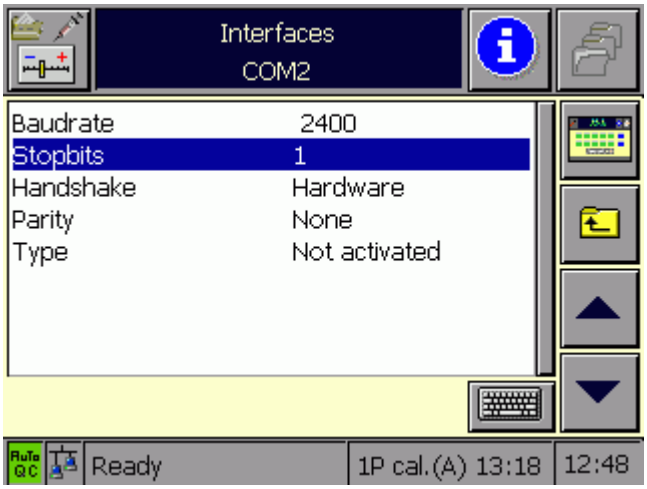
Press the **keyboard** button.



Select a baudrate matching the host's using the arrow buttons or directly pressing the line & press the **activation** button (above the arrow buttons).

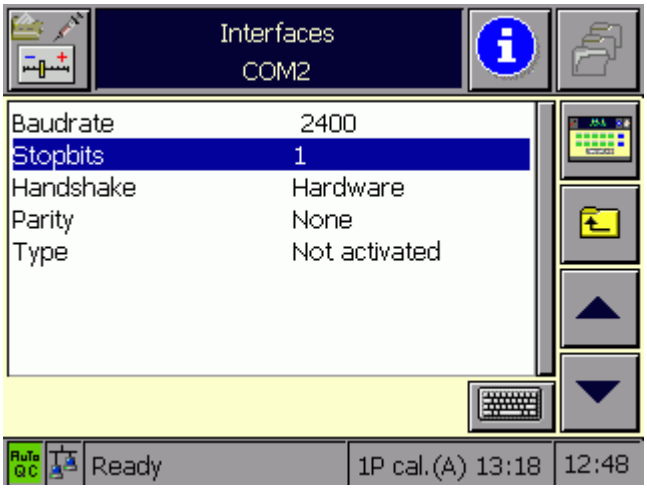


Select **stopbits** via arrow buttons or directly pressing the line.

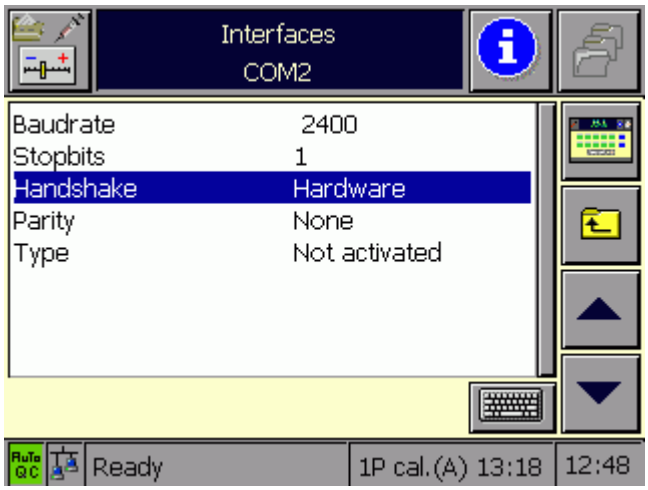


Press the **keyboard** button.

Select the number of stopbits matching the host's using the arrow buttons or directly pressing the line & press the **activation** button (above the arrow buttons).

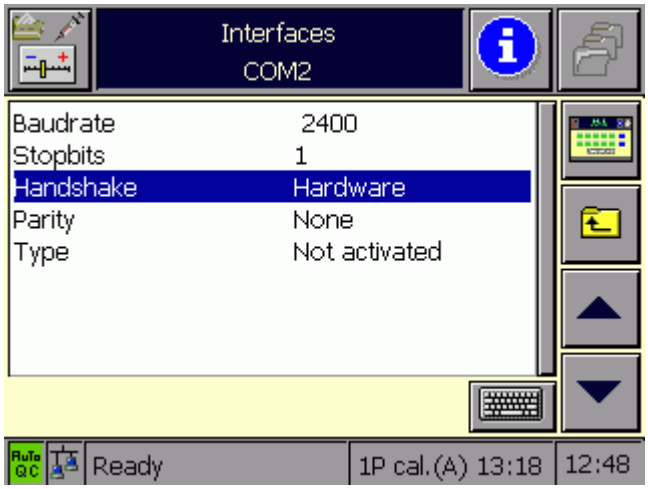


Select **handshake** via arrow buttons or directly pressing the line.

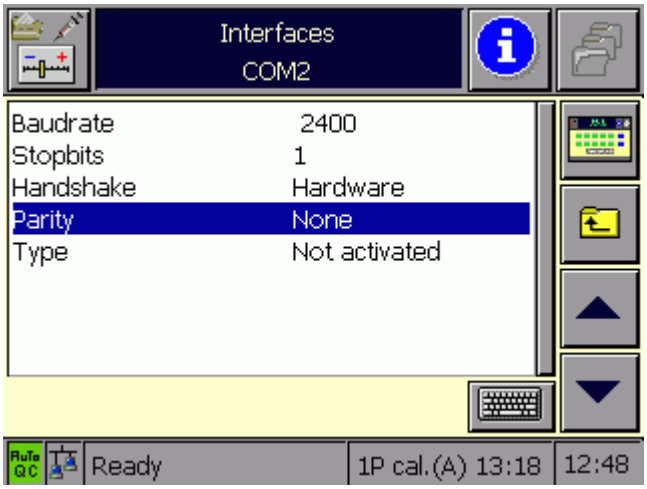


Press the **keyboard** button.

Select the handshake matching the host's via the arrow buttons or directly pressing the line & press the **activation** button (above the arrow buttons).

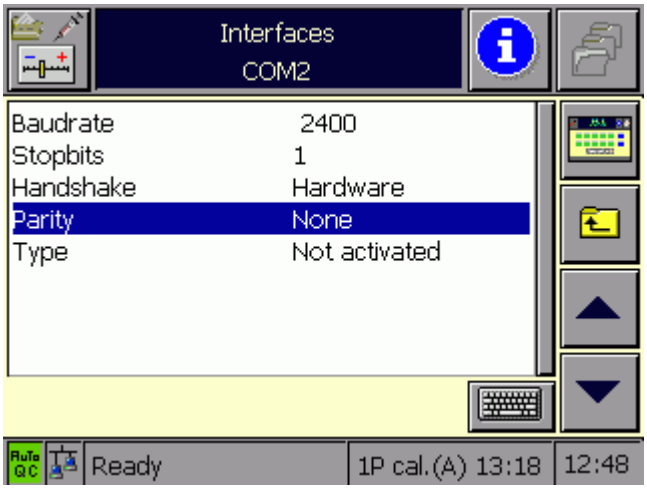


Select **parity** via arrow buttons or directly pressing the line.

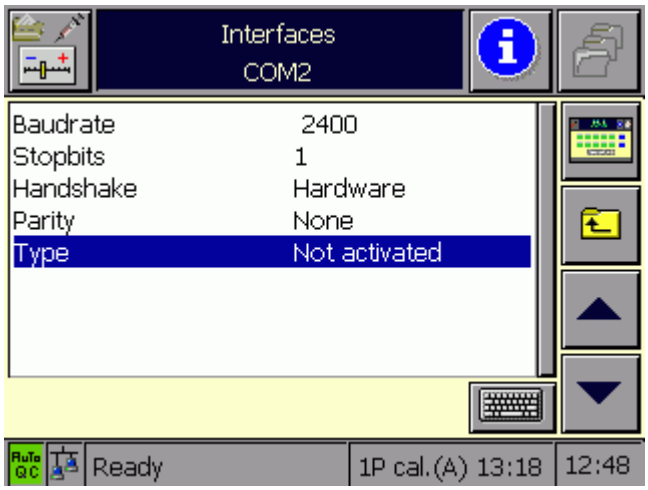


Press the **keyboard** button.

Select the parity matching the host's via the arrow buttons or directly pressing the line & press the **activation** button (above the arrow buttons).

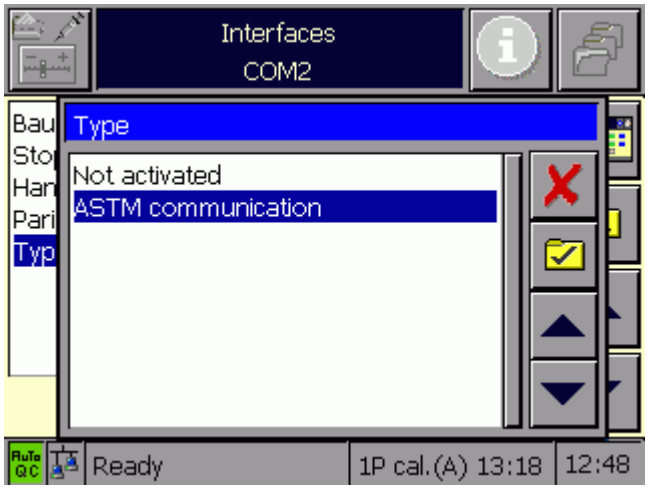


Select **type** via arrow buttons or directly pressing the line.

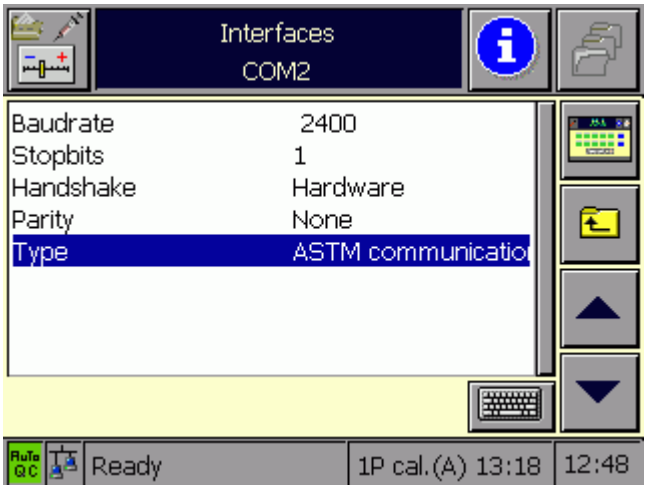


Press the **keyboard** button.

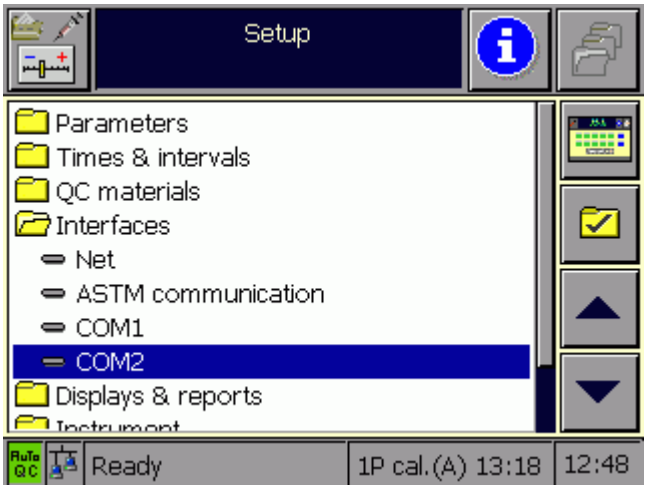
Note: In case "Service interface" is displayed for type, please contact Roche support to have it deactivated.



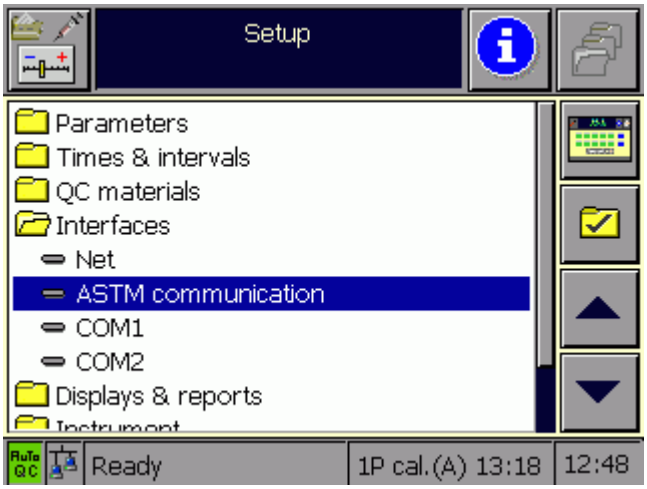
Select **ASTM communication** via the arrow buttons or directly pressing the line & press the **activation** button (above the arrow buttons).



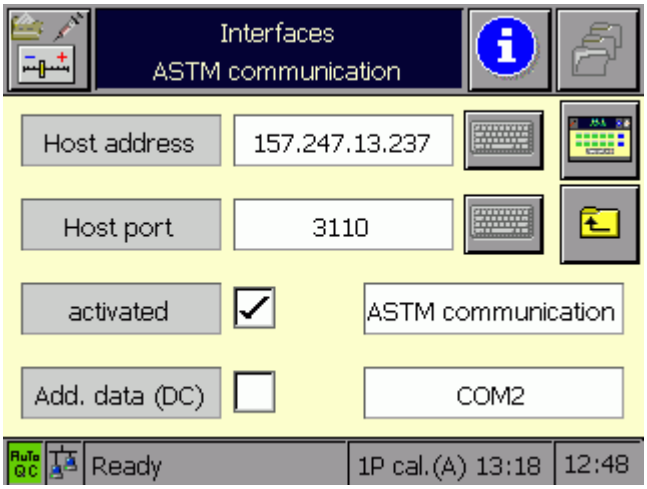
Press the **one level up** button (above the arrow buttons).



Select **ASTM communication** by using the arrow buttons or by directly pressing the line.



Press the **activation** button (above the arrow buttons).

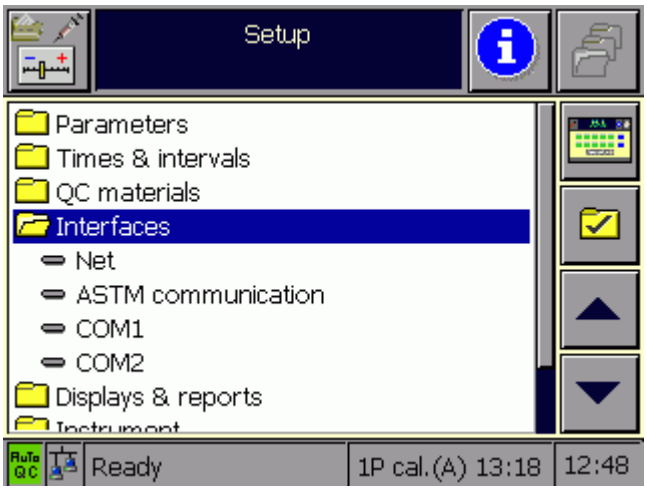


Make sure the **activated** checkbox is checked. In this case, measurement and QC data are transmitted, when the instrument changes back to the "Ready" screen. Make sure to check the "Add. Data (DC)" checkbox only, if calibration & maintenance data also is to be transmitted (not documented in this description).

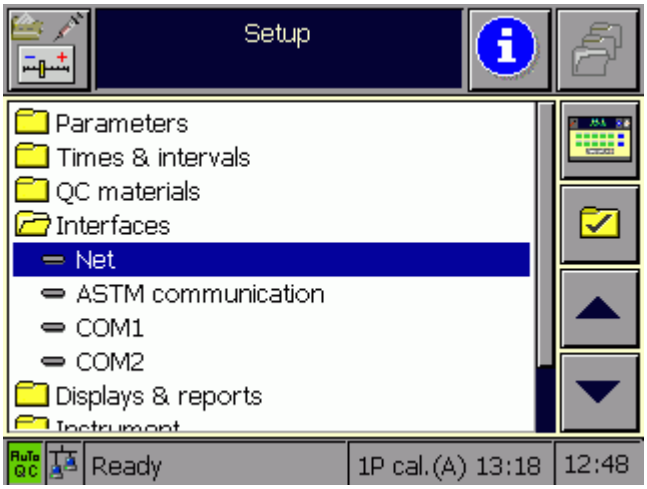
After having pressed the "**back to Ready**" button (above the one level up button) the **cobas b** 121 system/Roche OMNI C system is successfully configured for sending ASTM data via its COM 2 interface.

6.1.3 TCP/IP Connection

Make sure, that the instrument's Ethernet port (on the instrument's rear) is connected to a 10BaseT network port.



Select **Net** by using the arrow buttons or by directly pressing the line.



Press the **activation** button (above the arrow buttons).

Check the displayed **IP address**. In case it does not match the IP address dedicated by the hospital IT, press the keyboard button next to the IP address and change it.

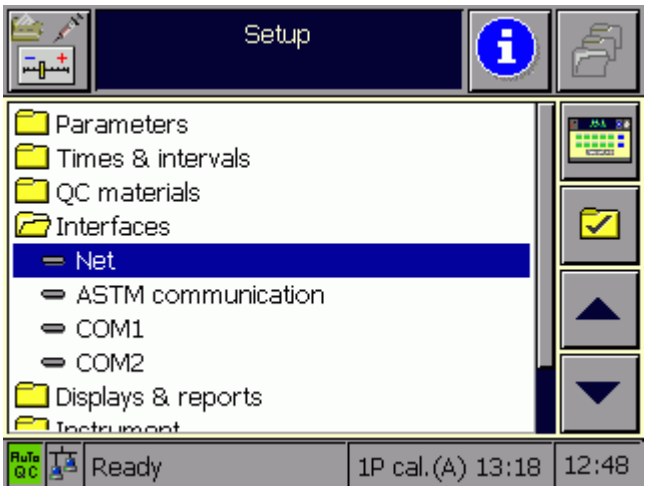
Also check the displayed **Subnet mask** and – if not matching the given sub-net mask – correct it after pressing the keyboard button.

Also check the displayed **Gateway** and – if not matching the dedicated gateway IP address – correct it after pressing the keyboard button.

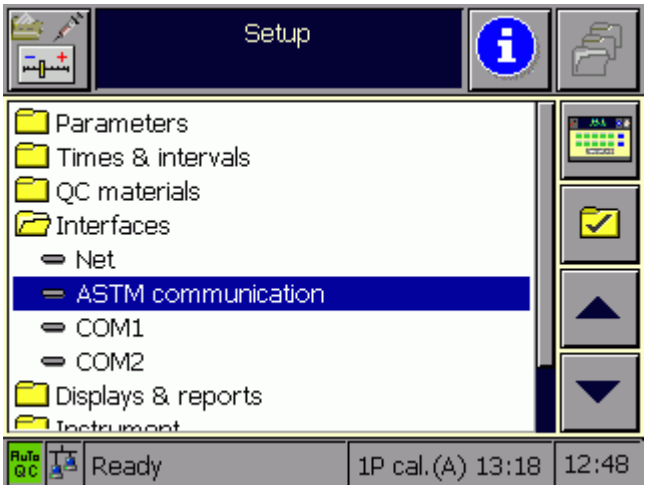
***Note:** Make sure, that the "Init at system start" checkbox is checked. In case the "Initialize" button is enabled, press it.*

***Hint:** Pressing the "More" and then the "Network test" button allows access to the PING functionality to allow for checking of the network connection. Furthermore the MAC address is displayed there, which might be useful for networks being generally managed using DHCP.*

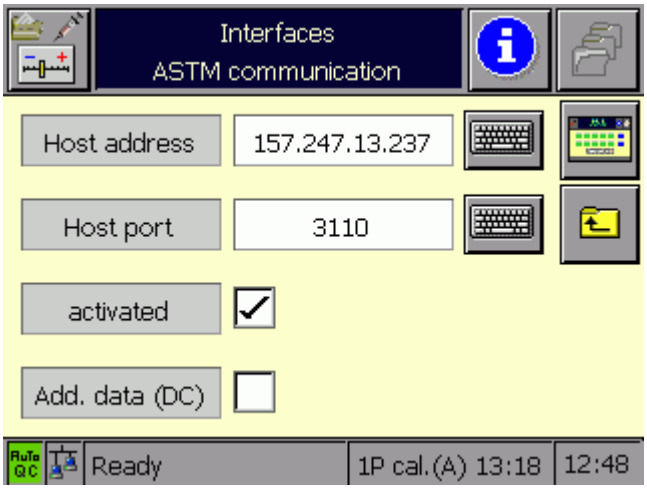
Press the one **level up** button.



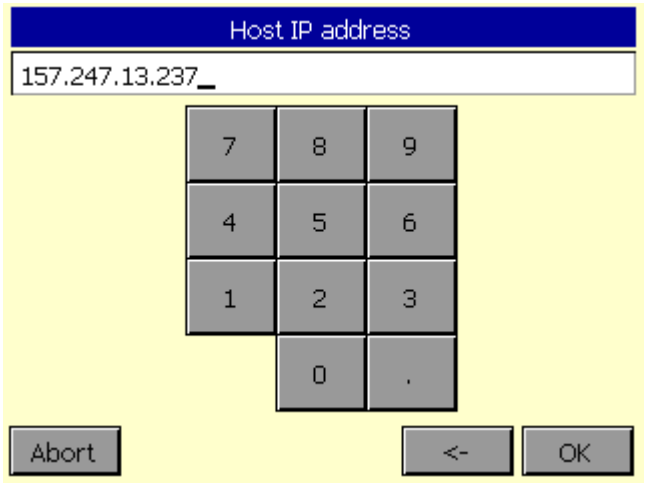
Select **ASTM communication** by using the arrow buttons or by directly pressing the line.



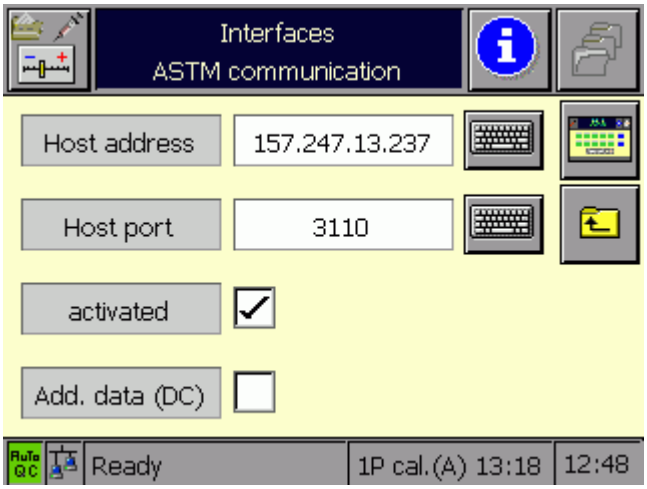
Press the **activation** button (above the arrow buttons).



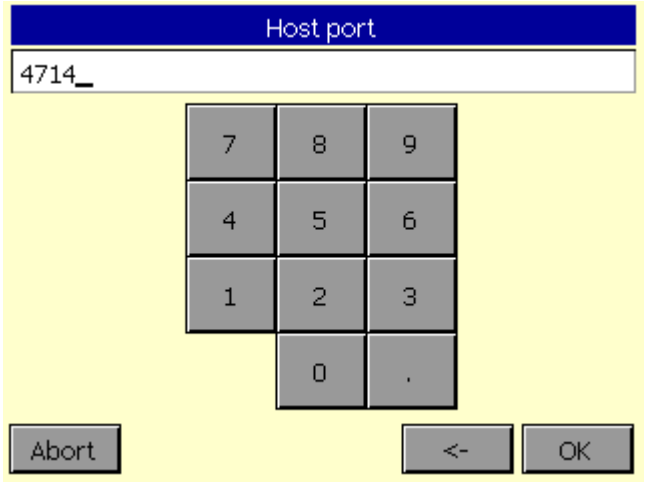
Press the **keyboard** button next to host address.



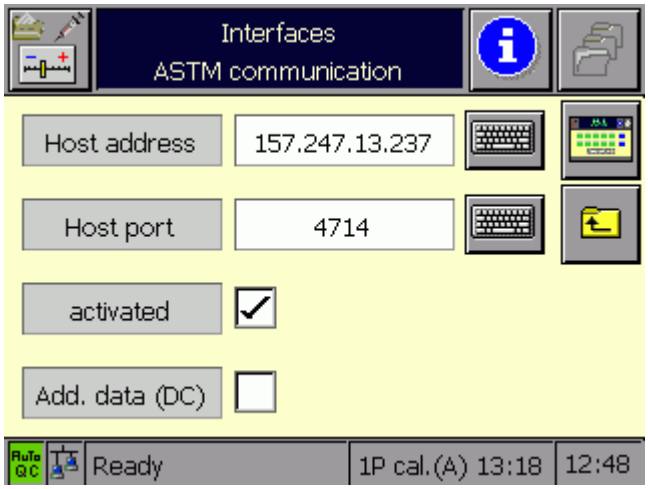
Type in the **host IP address** as specified by the hospital IT. Confirm the entry by pressing **OK**.



Press the **keyboard** button next to host port.



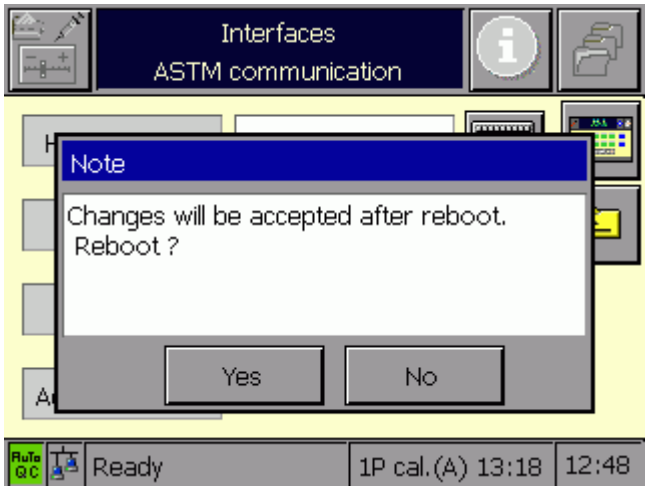
Type in the **host listener port** as specified by the hospital IT. Confirm the entry by pressing **OK**.



Make sure the **activated** checkbox is checked. In this case, measurement and QC data are transmitted, when the instrument changes back to the "Ready" screen. Make sure to tick the "Add. Data (DC)" checkbox only, if calibration & maintenance data also is to be transmitted (not documented in this description).

Note: Make sure, that the white "ASTM communication" and "COM 2" fields are not shown here. In case COM 2 is selected for ASTM communication, ASTM data can not be communicated over TCP/IP!

Press the **back to Ready** button.

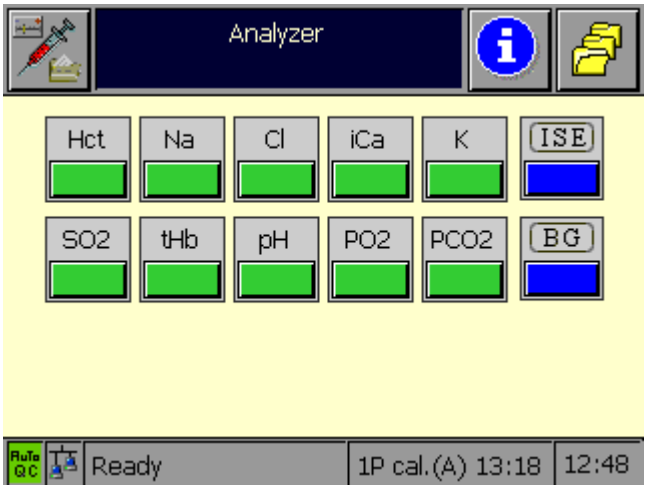


Accept the changes by pressing the **Yes** button.

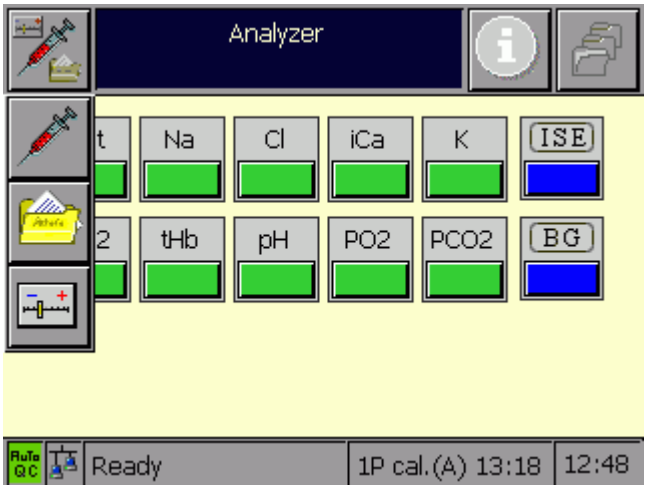
During the boot process, the instrument will initialize its Ethernet interface IP address and network connection. After sending the first data successfully, the network icon in the status bar will change to green. An icon changing back to grey indicates a loss of connection.

6.1.4 Patient Query Settings

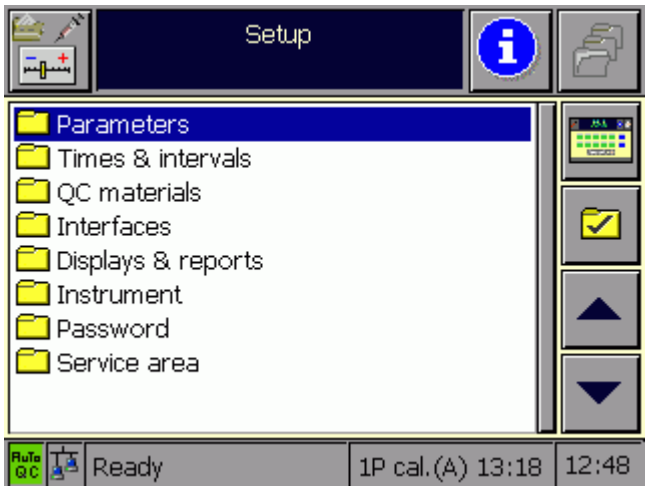
For instrument ease of use the patient query function should only be activated in case the connected information system is able to successfully answer the **cobas b** 121 system/Roche OMNI C system patient query.



Press the **task switch button** in the upper left corner of the screen.



Select the **setup** mode (the lowest icon).



Select **Instrument** either by using the arrow buttons or by directly pressing the line.

Press the **activation** button above the arrow buttons.

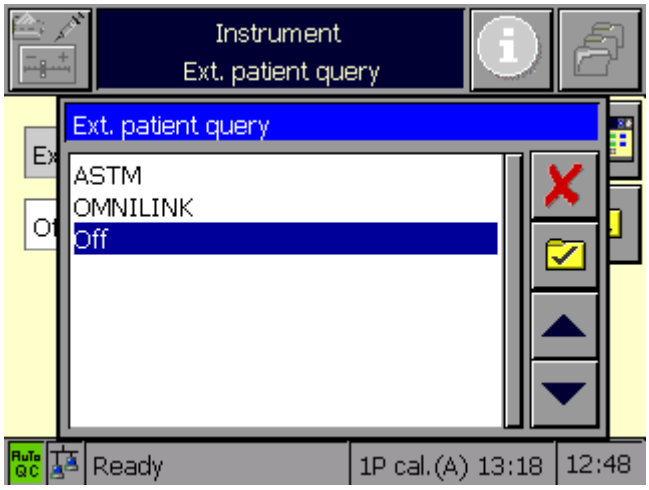
Select **Misc. settings** either by using the arrow buttons or by directly pressing the line.

Press the **activation** button above the arrow buttons.

Select **Ext. Patient query** either by using the arrow buttons or by directly pressing the line.

Press the **activation** button above the arrow buttons.

Press the **keyboard** button.



Select **ASTM** either by using the arrow buttons or by directly pressing the line.

Press the **activation** button above the arrow buttons.

Press the **back to ready** button above the one level up button.

Note: When a patient ID is entered during a measurement, the cobas b 121 system/Roche OMNI C system will query the connected information system for patient data. While the query is running, no data can be entered.

6.2 Resending of Results

To allow for resending of data from the database, **zoom** into the measurement, QC or calibration record to be resent and press the **Print** button. From the pop-up menu select one of the following options:

- **Print** (exclusively prints the displayed record)
- **ASTM Communication** (exclusively resends the displayed record)
- **Print & ASTM** (prints & resends the displayed record)

6.3 Table and Order of Transmitted Results

The table below lists all values which are transmitted as results and their order.

Name	Order	Remark
PH (H+)	1	Whether pH or H+ is transmitted in this place depends on which is set as measured parameter.
PCO2	2	
PO2	3	
Na	4	
K	5	
Cl	6	
ICa	7	
THb	8	
SO2	9	
Hct	10	
Temperature	11	
Baro	12	
cHCO3	13	
ctCO2(P)	14	
SO2(c)	15	
BE	16	

Name	Order	Remark
BEecf	17	
BB	18	
ctO2	19	
ctCO2(B)	20	
pHst	21	
cHCO3st	22	
HbI	23	
PAO2	24	
AaDO2	25	
a/AO2	26	
avDO2	27	
RI	28	
niCa	29	
AG	30	
pHt	31	
H+t	32	
PCO2t	33	
PO2t	34	
PAO2t	35	
AaDO2t	36	
a/AO2t	37	
RIt	38	
Hct(c)	39	
MCHC	40	
BO2	41	
BEact	42	
Osm	43	
OER	44	
Qs/Qt	45	

Name	Order	Remark
Qt	46	
P/F	47	
ALLEN Test	48	
A/F	49	
P50	50	
R	51	
FIO2	52	

6.4 Table of Measured Parameters

The table below lists all possible measured values that are available on the **cobas b** 121 system/Roche OMNI C system and can be transmitted to the host system within a measurement message.

Name	ID
pH	1
H+	2
PO2	3
PCO2	4
Hct	5
Na	6
K	7
Ca	8
Cl	9
tHb	10
SO2	11
Baro	31

6.5 Table of Calculated Parameters

The table below lists all possible calculated values that are available on the **cobas b** 121 system/Roche OMNI C and can be transmitted to the host system. For explanations, see the **cobas b** 121 system/Roche OMNI C Reference Manual, section 7.

Name	ID
H+	50
cHCO3	51
ctCO2(P)	52
BE	53
BE(act)	54
BEecf	55
BB	56
SO2(c)	58
P50	59
ctO2	60
ctCO2(B)	61
pHst	62
cHCO3st	63
PAO2	64
AaDO2	65
a/AO2	66
avDO2	67
RI	68
Qs/Qt	69
niCa	70
AG	71
pHt	72
H+t	73
PCO2t	74
PO2t	75
PAO2t	76

Name	ID
AaDO2t	77
a/AO2t	78
Rit	79
Hct (c)	80
MCHC	81
Osm	82
OER	83
BO2	84
Qt	86
P/F	88

6.6 Table of Input Parameters

The table below lists all input parameters that are available on the **cobas b** 121 system/Roche OMNI C and can be transmitted to the host system. For explanations and availability, see the **cobas b** 121 system/Roche OMNI C Reference Manual, section 3.2.5.

Name	ID	Transmitted in Record Type
Practice Patient ID	100	Patient Information Record
Laboratory Patient ID	101	Patient Information Record
Insurance Number	102	Patient Information Record
Last Name	103	Patient Information Record
First Name	104	Patient Information Record
Middle Initial	105	Patient Information Record
Suffix	106	Patient Information Record
Title	107	Patient Information Record
Mothers Name	108	Patient Information Record
Date of Birth	109	Patient Information Record
Age	110	Not transmitted
Sex	111	Patient Information Record
Race	112	Patient Information Record
Address	113	Patient Information Record

Name	ID	Transmitted in Record Type
Phone Number	114	Patient Information Record
Physician	115	Patient Information Record
Height	116	Patient Information Record
Weight	117	Patient Information Record
Diagnosis	118	Patient Information Record
Medications	119	Patient Information Record
Diet	120	Patient Information Record
Admission Date	121	Patient Information Record
Admission Time	122	Patient Information Record
Discharge Date	123	Patient Information Record
Discharge Time	124	Patient Information Record
Admission Status	125	Patient Information Record
Location	126	Patient Information Record
Diagnostic Code Type	127	Patient Information Record
Religion	128	Patient Information Record
Marital Status	129	Patient Information Record
Isolation Status	130	Patient Information Record
Patient Language	131	Patient Information Record
Hospital Service	132	Patient Information Record
Hospital Institut	133	Patient Information Record
Dosage Category	134	Patient Information Record
Measurement Time	135	Header Record
Measurement Date	136	Header Record
Time Changed	137	Not transmitted
Date Changed	138	Not transmitted
Operator ID	139	First Result Record
Remark	140	Comment Record
Specimen ID (Accession No)	141	Test Order Record

Name	ID	Transmitted in Record Type
Samples	142	Not transmitted
Order ID (sample No)	143	Test Order Record
Acceptor	144	Not transmitted
Date Drawn	145	Not transmitted
Time Drawn	146	Not transmitted
Danger Code	147	Test Order Record
Clinic Info	148	Test Order Record
Sample Type	149	Test Order Record
Blood Type	150	Test Order Record
Puncture Site	151	Test Order Record
ALLEN Flag	152	Result Record
Container	153	Test Order Record
A/F	154	Result Record
Pat.Temp.	155	Result Record
P_{50}	156	Result Record
R	157	Result Record
FIO_2	158	Result Record
24h Urine	159	Result Record
Vent Mode	160	Result Record
VT	161	Result Record
MV	162	Result Record
PIP	163	Result Record
Ti	164	Result Record
Te	165	Result Record
SRATE	166	Result Record
ARATE	167	Result Record
PEEP	168	Result Record
MAP	169	Result Record
Flow	170	Result Record
HbI	200	Result Record

6.7 Table of Sample Types & Blood Types

Sample Types	Blood Types
Whole blood	Arterial
Aqueous solution	Capillary
Serum/plasma	Mixed venous
Acetate	Venous
Bicarbonate	Unknown

6.8 Table of QC Parameters

The table below lists all possible values that are available on the **cobas b** 121 system/Roche OMNI C for quality control and can be transmitted to the host system with a QC message.

Name	ID
Na	600
Cl	601
pH/H+ (settings dependent)	602
iCa	603
K	604
PO2	605
PCO2	606
tHb	607
SO2	608
Hct	609