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# **cobas b 221 system**

## ASTM Interface Description



Diagnostics

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## 1. Introduction & General Information

The **cobas b 221** system/Roche OMNI S 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 system's built in UTP network port as well as via serial connection over the COM 1 port. For a description of the low level protocols used, please see Low Level Protocols, page 21. For information of setting up the connection, please see the APPENDIX, Connection Settings, page 31. This description covers the protocol as used with version 5.0

## 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	M	Manufacturer Record
P	Patient Record	Q	Request Information Record
O	Test Order Record	L	Message Terminator Record
R	Result 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. multiple range information  
|7.350^7.450^reference\7.200^7.600^critical|

#### 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^jr.^M.D.|

#### 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 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<sup>th</sup> 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 ^ (caret) 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:

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	Instrument ID, manufacturer name, instrument type, software version, protocol version, serial number and IP address; 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	Receiving application name and IP address; separated by component delimiters.
11	Comment or Special Instructions	Message type. M = measurement results, QC = quality control results, SR^REAL = calibration results, LSU^U12 = maintenance data, PQ = patient information query.

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

### 3.2.1 Example

```
H|\^&|||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88||||||↵
LSU^U12|P|1394-97|20040615164743<CR>
```

## 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 Information Query. A QC Report contains a Patient Information Record without data due to ASTM standard compliance necessities. The Patient Information record consists of the following fields:

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

Field #	Field Name	Comment
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^Suffix^Title. 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	Patient ethnic origin. Generic text (as entered at the instrument).
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.
16	Special field 2	Not used by the instrument.
17	Patient Height	Format value^unit.

Field #	Field Name	Comment
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
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

### 3.3.1 Example

P|1||123456|Amex123|Sample ^ Josephine ^ X ^ jr. ^ M.D.|Good|  
 20691202|Female|Caucasian|1 Draft Avenue, Omaha|  
+43 316 27787-7349	Trapper John, M.D.			169.0 ^ cm	72.0 ^ kg	Birth
None	Steak and Gravy			20030427103200	Admitted	
Third Floor, Delivery	Diag Code123		Catholic	Separated		
Isolation 123	Estonian	Intensive	Maternity Clinic	Dosage 123<CR>		

## 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 221 system/ Roche OMNI S** system only is transmitted to the host computer as part of the measurement report.

The Test Order record consists of the following fields:

Field #	Field Name	Comment
1	Record Type ID	Required, always 0
2	Sequence#	Required, sequential number
3	Specimen ID	Account or bar code number
4	Instrument Specimen ID	Order ID ^ Measurement ID ^ ^ ^ Sample Container.

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	Not used by the instrument.
12	Action code	Not used by the instrument.
13	Danger code	Generic text (as entered at the instrument).
14	Relevant clinical information	Clinic Info. Generic text (as entered at the instrument).
15	Date/Time specimen received	Not used by the instrument.
16	Specimen descriptor	For measurement: Sample type, blood type and puncture site; separated by component delimiters.  For quality control: Material name, level, lot number and material base; separated by component delimiters.

Field #	Field Name	Comment
17	Ordering Physician	Not used by the instrument.
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.



Field #	Field Name	Comment
29	Nosocomial Infection Flag	Not used by the instrument.
30	Specimen Service	Not used by the instrument.
31	Specimen Institution	Not used by the instrument.
<CR>	Carriage Return	Required. Record Terminator

### 3.4.1 Example

O|1|spec123|order123^33^ ^ ^Syringe|||||danger123|Clinic123|  
 |Aqueous solution^Arterial^A. femoralis I.<CR>

## 3.5 Result Record

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

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.

Field #	Field Name	Comment
6	Reference ranges	Reference range of the analyte. Format is lower limit ^ upper limit ^ limit name. Multiple ranges are separated by repeat delimiters.
7	Result Abnormal Flags	N      Normal A      Abnormal <sup>1</sup> L      Below reference range H      Above reference range LL     Below critical range HH     Above critical range <      Off low scale of instrument >      Off high scale of instrument
8	Nature of abnormality testing	A, S, N or empty.
9	Result Status	F      Final
10	Date of Change in Instrument Normative Values	Not used by instrument.
11	Operator Identification	Identifies operator who performed the test (instrument operator). <i>Note: Only transmitted in the first result record.</i>
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 <i>Note: Only transmitted in the first result record.</i>
14	Instrument Identification	Not used by the instrument.

<sup>1</sup> This flag is sent in case no value is available due to reasons different from being off instrument scale (e.g. not selected for measurement, not calibrated, locked by QC).

Field #	Field Name	Comment
<CR>	Carriage Return	Required. Record Terminator

### 3.5.1 Example

R|1|^ ^ ^pH^ ^ ^M^1|7.185||7.350^7.450^reference↵  
 \7.200^7.600^critical|LL||F||oper123||20040615183711<CR>

## 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 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:

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.

Field #	Field Name	Comment
9	Requesting Physician Name	Not used by the instrument.
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

### 3.6.1 Example

Q|1|123456|||||||D<CR>

## 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. The Comment record consists of the following fields:

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

Field #	Field Name	Comment
1	Record Type ID	Required, always is R.
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

### 3.7.1 Example

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

## 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:

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

### 3.8.1 Example

L|1|N<CR>

## 3.9 Manufacturer Information Record

For the **cobas b 221** system/Roche OMNI S system, this record is used for transmitting calibration, error and maintenance data only.

The Manufacturer Information record will consist of the following:

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, error or maintenance information.
<CR>	Carriage Return	Required. Record Terminator

### 3.9.1 Example

M|1|EQU^RO^OS^1|GSS|20040615164641|OP||N<CR>

## 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 221 system/** Roche OMNI S system implementation can be found in the following.

#### 4.2.1 Control Characters

Control characters that are used for ASTM communications:

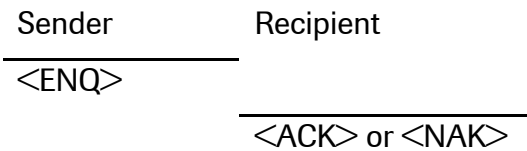
ASCII	Decimal	Hex	Control char.	Comment
<STX>	2	0x2	^B	<b>Start of TeXt</b>
<ETX>	3	0x3	^C	<b>End of TeXt</b>
<EOT>	4	0x4	^D	<b>End Of</b> Transmission
<ENQ>	5	0x5	^E	<b>ENQ</b> uiry
<ACK>	6	0x6	^F	<b>ACK</b> nowledge
<LF>	10	0xA	^J	<b>Line Feed</b>
<CR>	13	0xD	^M	<b>Carriage Return</b>
<NAK>	21	0x15	^U	<b>Negative AcK</b> nowledge
<ETB>	23	0x17	^W	<b>End of Trans. Block</b>

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 **cobas b 221 system/Roche OMNI S system** 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.

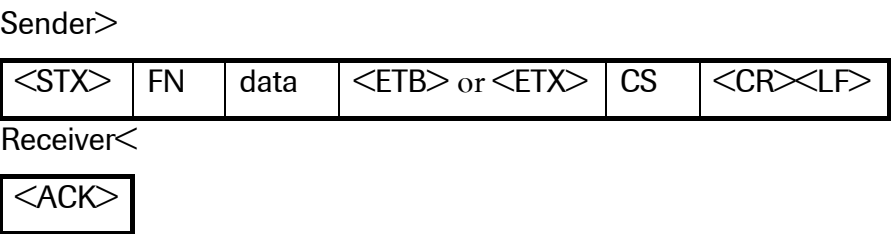


If an <ACK> character is received from the host, the establishment phase is successful, and the transfer phase follows. If a <NAK> character is received from the host, the instrument waits a minimum of 10 seconds, then resends the <ENQ> after receipt of the <NAK> and repeats this loop until an ACK is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





## 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.  <div data-bbox="667 1111 1453 1180" style="margin-left: 40px;"> <p>&lt;STX&gt; FN data &lt;ETB&gt; CS &lt;CR&gt;&lt;LF&gt; ⇐ Intermediate frame(s)</p> <p>&lt;STX&gt; FN data &lt;ETX&gt; CS &lt;CR&gt;&lt;LF&gt; ⇐ End frame</p> </div>
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)**

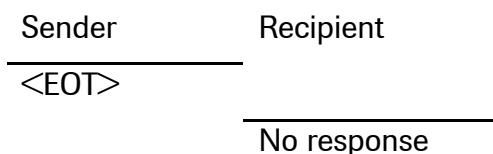
The <EOT> reply signifies the last frame was received successfully and the receiver is prepared to receive another frame, but requests the sender to stop transmitting data. See interrupts below.

#### 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.



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.

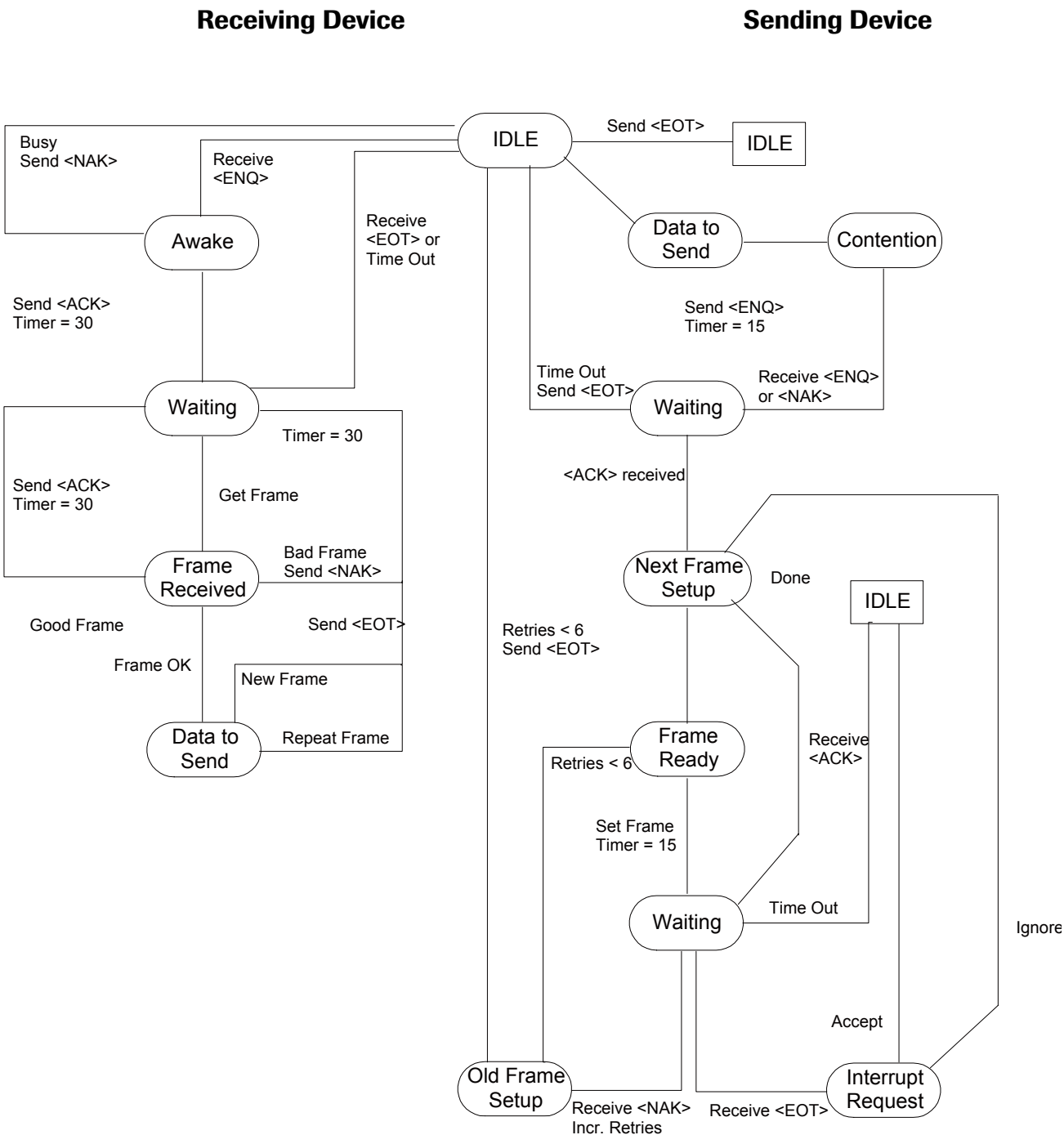
If the receiver detects contention and no <ENQ> is received within 20 seconds, the receiver regards the data link to be in the neutral state.

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



## 5. Data Examples

### 5.1 Measurement Report

```

H|\^&||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88|||||M|P|1394-97|20040615184647
P|1||123456|Amex123|Sample^Josephine^X^jr.^M.D.|Good|20691202|Female|Caucasian|1 Draft
Avenue, Omaha||+43 316 27787-7349|Trapper John, M.D.||169.0^cm|72.0^kg|Birth|None|Steak and
Gravy|||20030427103200|Admitted|Third Floor, Delivery|Diag Code123||Catholic|Separated|Isolation
123|Estonian|Intensive|Maternity Clinic|Dosage 123
O|1|spec123|order123^33^ ^ ^ ^Syringe|||||||danger123|Clinic123||Aqueous solution^Arterial^A.
femoralis l.
R|1|^ ^ ^pH^ ^ ^M^1|7.185||7.350^7.450^reference\7.200^7.600^critical|LL||F||oper123||2004061518
3711
R|2|^ ^ ^PO2^ ^ ^M^3||mmHg|80.0^100.0^reference\60.0^800.0^critical|A||F
R|3|^ ^ ^PCO2^ ^ ^M^4||mmHg|35.0^45.0^reference\20.0^60.0^critical|A||F
R|4|^ ^ ^Hct^ ^ ^M^5||%|35.0^50.0^reference\25.0^65.0^critical|A||F
R|5|^ ^ ^Na^ ^ ^M^6|118.7|mmol/l|135.0^148.0^reference\125.0^160.0^critical|LL||F
R|6|^ ^ ^K^ ^ ^M^7||mmol/l|3.50^4.50^reference\2.80^6.00^critical|A||F
R|7|^ ^ ^Ca^ ^ ^M^8||mmol/l|1.120^1.320^reference\1.050^1.500^critical|A||F
R|8|^ ^ ^Cl^ ^ ^M^9|85.1|mmol/l|98.0^107.0^reference\80.0^115.0^critical|L||F
R|9|^ ^ ^tHb^ ^ ^M^10||g/dL|11.5^17.4^reference\8.0^23.0^critical|A||F
R|10|^ ^ ^SO2^ ^ ^M^11|29.5||%|75.0^99.0^reference\60.0^100.0^critical|LL||F
R|11|^ ^ ^O2Hb^ ^ ^M^12|48.1||%|95.0^99.0^reference\80.0^100.0^critical|LL||F
R|12|^ ^ ^COHb^ ^ ^M^13||%|0.5^2.5^reference\0.0^10.0^critical|A||F
R|13|^ ^ ^MetHb^ ^ ^M^14||%|0.4^1.5^reference\0.0^5.0^critical|A||F
R|14|^ ^ ^HHb^ ^ ^M^16||%|1.0^5.0^reference\0.0^20.0^critical|A||F
R|15|^ ^ ^Bili^ ^ ^M^17||umol/L|24^149^reference\0^256^critical|A||F
R|16|^ ^ ^Glu^ ^ ^M^18|5.4|mmol/l|3.3^6.1^reference\2.8^7.8^critical|N||F
R|17|^ ^ ^Lac^ ^ ^M^19|9.5|mmol/l|0.4^2.2^reference\0.2^5.0^critical|HH||F
R|18|^ ^ ^Urea^ ^ ^M^24||mmol/l|2.5^6.4^reference\0.5^35.7^critical|A||F
R|19|^ ^ ^Baro^ ^ ^M^31|727.8|mmHg||N||F
R|20|^ ^ ^H+^ ^ ^C^50|65.3|nmol/L||N||F
R|21|^ ^ ^cHCO3^ ^ ^C^51||mmol/l||A||F
R|22|^ ^ ^ctCO2(P)^ ^ ^C^52||mmol/l||A||F
R|23|^ ^ ^BE^ ^ ^C^53||mmol/l||A||F
R|24|^ ^ ^BE(act)^ ^ ^C^54||mmol/l||A||F
R|25|^ ^ ^BEecf^ ^ ^C^55||mmol/l||A||F
R|26|^ ^ ^BB^ ^ ^C^56||mmol/l||A||F
R|27|^ ^ ^SO2(c)^ ^ ^C^58||%||A||F
R|28|^ ^ ^P50^ ^ ^C^59||mmHg||A||F
R|29|^ ^ ^FO2Hb^ ^ ^C^89|0.481||N||F
R|30|^ ^ ^ctO2^ ^ ^C^60|8.3|vol%||N||F
R|31|^ ^ ^ctCO2(B)^ ^ ^C^61||mmol/l||A||F
R|32|^ ^ ^pHst^ ^ ^C^62||A||F
R|33|^ ^ ^cHCO3st^ ^ ^C^63||mmol/l||A||F
R|34|^ ^ ^PAO2^ ^ ^C^64||mmHg||A||F
R|35|^ ^ ^AaDO2^ ^ ^C^65||mmHg||A||F
R|36|^ ^ ^a/AO2^ ^ ^C^66||%||A||F
R|37|^ ^ ^avDO2^ ^ ^C^67||vol%||A||F
R|38|^ ^ ^RI^ ^ ^C^68||%||A||F
R|39|^ ^ ^Qs/Qt^ ^ ^C^69||%||A||F

```

```

R|40|^|^OER^^^C^83||%||A||F
R|41|^|^niCa^^^C^70||mmol/l||A||F
R|42|^|^AG^^^C^71||mmol/l||A||F
R|43|^|^pht^^^C^72|7.185||N||F
R|44|^|^cHt^^^C^73|65.3|nmol/L||N||F
R|45|^|^PCO2t^^^C^74||mmHg||A||F
R|46|^|^PO2t^^^C^75||mmHg||A||F
R|47|^|^PAO2t^^^C^76||mmHg||A||F
R|48|^|^AaDO2t^^^C^77||mmHg||A||F
R|49|^|^a/AO2t^^^C^78||%||A||F
R|50|^|^Rlt^^^C^79||%||A||F
R|51|^|^Hct(c)^^^C^80||%||A||F
R|52|^|^MCHC^^^C^81||g/dL||A||F
R|53|^|^Osm^^^C^82|262|mOsm/kg||N||F
R|54|^|^BO2^^^C^84||vol%||A||F
R|55|^|^BUN^^^C^85||mg/dL||A||F
R|56|^|^Qt^^^C^86||vol%||A||F
R|57|^|^PFIndex^^^C^88||mmHg||A||F
R|58|^|^ALLEN test^^^I^152|On||N||F
R|59|^|^Pat.Temp^^^I^155|37.0|C||N||F
R|60|^|^R^^^I^157|0.84||N||F
R|61|^|^FIO2^^^I^158|0.21||N||F
R|62|^|^tHb(e)^^^I^171|12.0|g/dL||N||F
R|63|^|^Hb Factor^^^I^172|3.0||N||F
R|64|^|^24h Urine^^^I^159||ml||N||F
R|65|^|^Vent Mode^^^I^160||N||F
R|66|^|^VT^^^I^161||N||F
R|67|^|^MV^^^I^162||N||F
R|68|^|^PIP^^^I^163||cmH2O||N||F
R|69|^|^Ti^^^I^164||s||N||F
R|70|^|^Te^^^I^165||s||N||F
R|71|^|^SRATE^^^I^166||N||F
R|72|^|^ARATE^^^I^167||N||F
R|73|^|^PEEP^^^I^168||cmH2O||N||F
R|74|^|^MAP^^^I^169||cmH2O||N||F
R|75|^|^Flow^^^I^170||l/min||N||F
R|76|^|^Age (A/F)^^^I^110|> 1 year||N||F
R|77|^|^Date drawn^^^I^145|20040615||N||F
R|78|^|^Time drawn^^^I^146|182500||N||F
R|79|^|^Date changed^^^I^138|20040615||N||F
R|80|^|^Time changed^^^I^137|184645||N||F
R|81|^|^Department^^^I^174|Alpha||N||F
R|82|^|^Accepted by^^^I^144|Acceptor||N||F
R|83|^|^Billing code^^^I^173|bill123||N||F
R|84|^|^Remark^^^I^140|A Remark||N||F
L|1|N

```

## 5.2 QC Report

```

H|\^&||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88|||||QC|P|1394-97|20040615183318
P|1
O|1|||||AUTO-TROL PLUS B^1^21723202^aqueous
C|1||The Remark|G
R|1|^ ^ ^Bili^ ^ ^M^615|104|umol/L| 87^ 115|N||F||oper123||20040615182731
R|2|^ ^ ^Ca^ ^ ^M^603|1.797|mmol/l|1.420^1.720|H||F
R|3|^ ^ ^Cl^ ^ ^M^601|84.0|mmol/l|81.0^89.0|N||F
R|4|^ ^ ^COHb^ ^ ^M^611|22.9|%|20.8^25.8|N||F
R|5|^ ^ ^Glu^ ^ ^M^616|5.5|mmol/l| 4.7^ 6.5|N||F
R|6|^ ^ ^Hct^ ^ ^M^609|53.6|%|50.0^60.0|N||F
R|7|^ ^ ^HHb^ ^ ^M^614|18.1|%|16.3^20.3|N||F
R|8|^ ^ ^K^ ^ ^M^604||mmol/l|2.80^3.20|A||F
R|9|^ ^ ^Lac^ ^ ^M^617|9.4|mmol/l| 7.2^11.2|N||F
R|10|^ ^ ^MetHb^ ^ ^M^612|12.0|%|10.6^13.6|N||F
R|11|^ ^ ^Na^ ^ ^M^600|121.7|mmol/l|117.0^125.0|N||F
R|12|^ ^ ^O2Hb^ ^ ^M^610|47.0|%|42.2^50.2|N||F
R|13|^ ^ ^PCO2^ ^ ^M^606||mmHg|61.0^69.0|A||F
R|14|^ ^ ^pH^ ^ ^M^602|7.201|7.150^7.210|N||F
R|15|^ ^ ^PO2^ ^ ^M^605||mmHg|39.0^63.0|A||F
R|16|^ ^ ^SO2^ ^ ^M^608|72.3|%|67.5^75.5|N||F
R|17|^ ^ ^tHb^ ^ ^M^607|7.8|g/dL|6.9^8.3|N||F
R|18|^ ^ ^Urea^ ^ ^M^619||mmol/l|20.0^26.0|A||F
L|1|N

```

## 5.3 Calibration Report

```

H|\^&||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88|||||SR^REAL|P|1394-97|20040615174522
M|1|SR^RO^OS^1|337^Glu^Lin|4.43|| 4.00^ 3.00^ 4.90|N^0|SYSTEM|20040615174521
M|2|SR^RO^OS^1|338^Glu^3P Sense|5.86|nA| 10.00^ 0.50^100.00|N^0
M|3|SR^RO^OS^1|340^Lac^Lin|3.59|| 4.00^ 3.00^ 4.90|N^0
M|4|SR^RO^OS^1|341^Lac^3P Sense|4.84|nA| 10.00^ 0.50^100.00|N^0
M|5|SR^RO^OS^1|342^BSA^1P Sense|1.88|nA| 0.00^ -5.00^ 5.00|N^0
M|6|SR^RO^OS^1|343^BSA^3P Sense|32.00|nA| 10.00^ 0.50^100.00|N^0
M|7|SR^RO^OS^1|344^Urea^1P Pot||mV| 31.00^ 20.00^ 40.00|A^2028
M|8|SR^RO^OS^1|345^Urea^Lin|| 1.65^ 1.60^ 1.90|A^2028
M|9|SR^RO^OS^1|346^Urea^3P Pot|605.22|mV| -3.00^ -10.00^ 5.00|N^0
M|10|SR^RO^OS^1|346^Urea^4P Pot||mV| -3.00^ -10.00^ 5.00|A^8076
M|11|SR^RO^OS^1|348^Urea K^4P Pot||mV| 17.00^ 10.00^ 20.00|A^2028
M|12|SR^RO^OS^1|349^NH4^3P Pot|11.65|mV| 15.00^ 10.00^ 20.00|N^0
M|13|SR^RO^OS^1|350^NH4^4P Pot|10.26|mV| 12.00^ 5.00^ 15.00|N^0
M|14|SR^RO^OS^1|31^Baro|728.0|mmHg| 0.0^450.0^800.0|N^0
M|15|SR^RO^OS^1|374^Cal type|System cal||N^0
L|1|N

```

## 5.4 Maintenance Report

```
H|\^&||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88|||||LSU^U12|P|1394-97|20040615164743
M|1|EQU^RO^OS^1|GSS|20040615164742|OP||N
M|2|EQP^RO^OS^1|1^LOG||20040615164742||1214^2^8^1^-1^Glu-Lac-Urea - 21530107
L|1|N
```

## 5.5 Error Report

```
H|\^&||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88|||||LSU^U12|P|1394-97|20040615164642
M|1|EQU^RO^OS^1|GSS|20040615164641|OP||N
M|2|EQP^RO^OS^1|1^LOG||20040615164641||1214^5^1^1^10154^Measuring chamber cover
MSS open^System
L|1|N
```

## 5.6 Patient Information Query

```
H|\^&||GSS^Roche^OMNI S^V5.0^1^115^10.124.67.88|||||PQ|P|1394-97|20040615163836
Q|1|123456|||||||D
L|1|N
```



## 6. APPENDIX

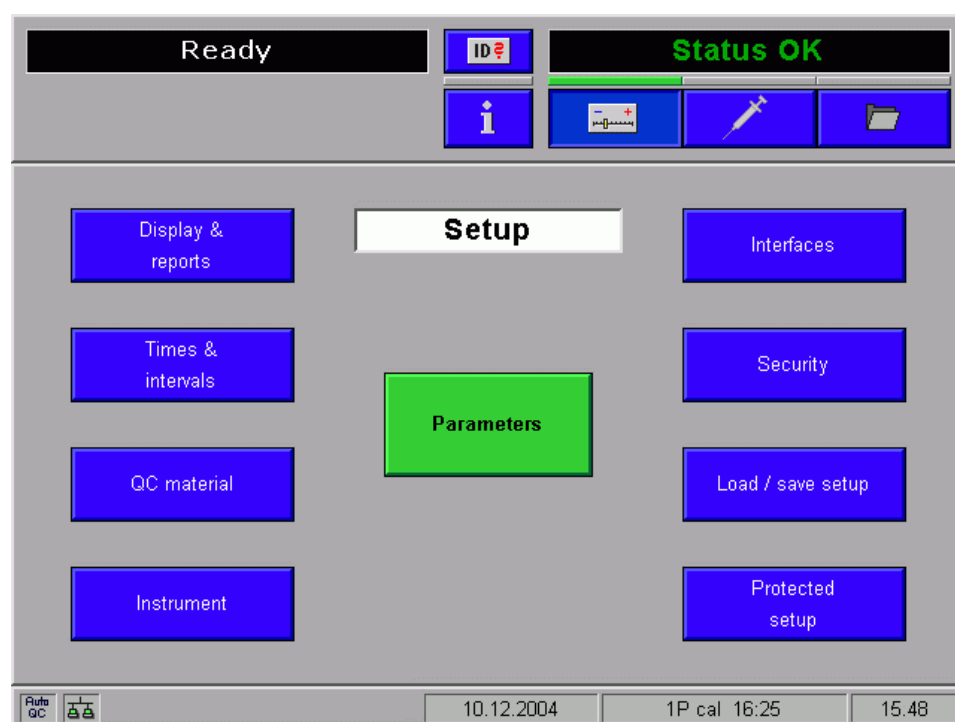
### 6.1 Connection Settings

#### 6.1.1 General

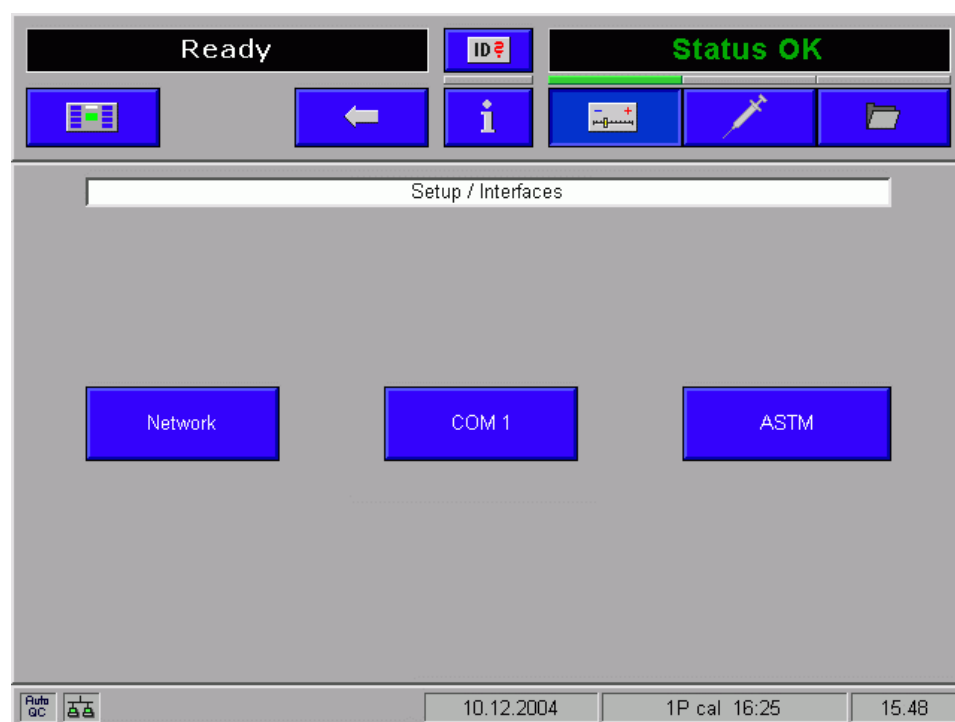
The **cobas b** 221 system/Roche OMNI S system connection settings are done in the Interface section of the setup mode. To get there, please follow the steps listed below:



Press set-up button in the upper right area of the screen.



Press the **Interfaces** button.



To proceed, please see Network Settings, Serial Settings and ASTM Settings.

### 6.1.2 Network Settings

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

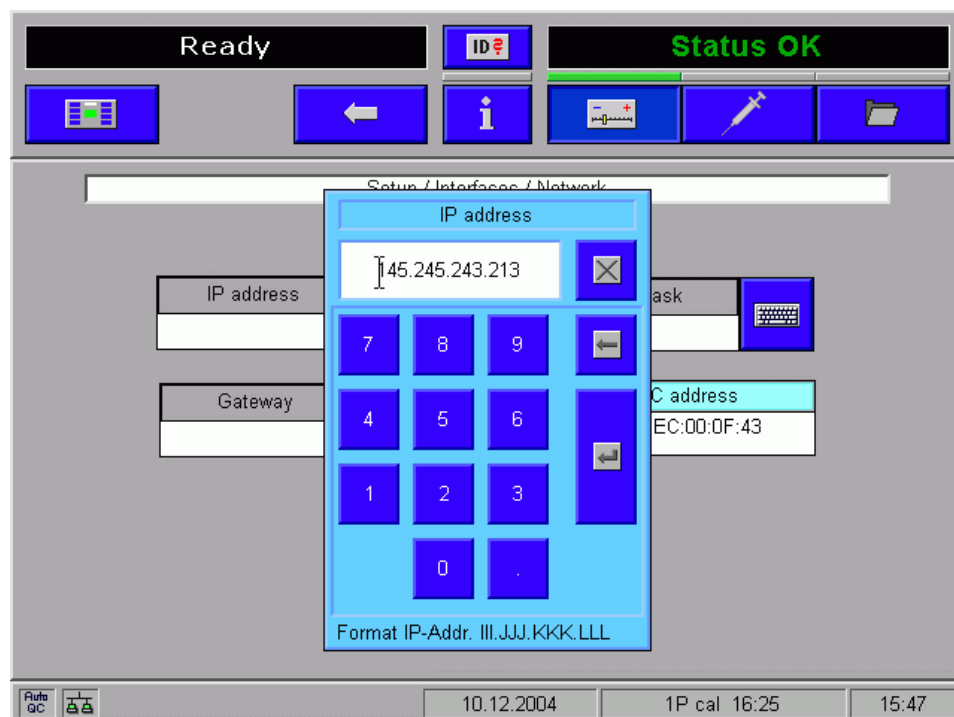



Press the Network button.

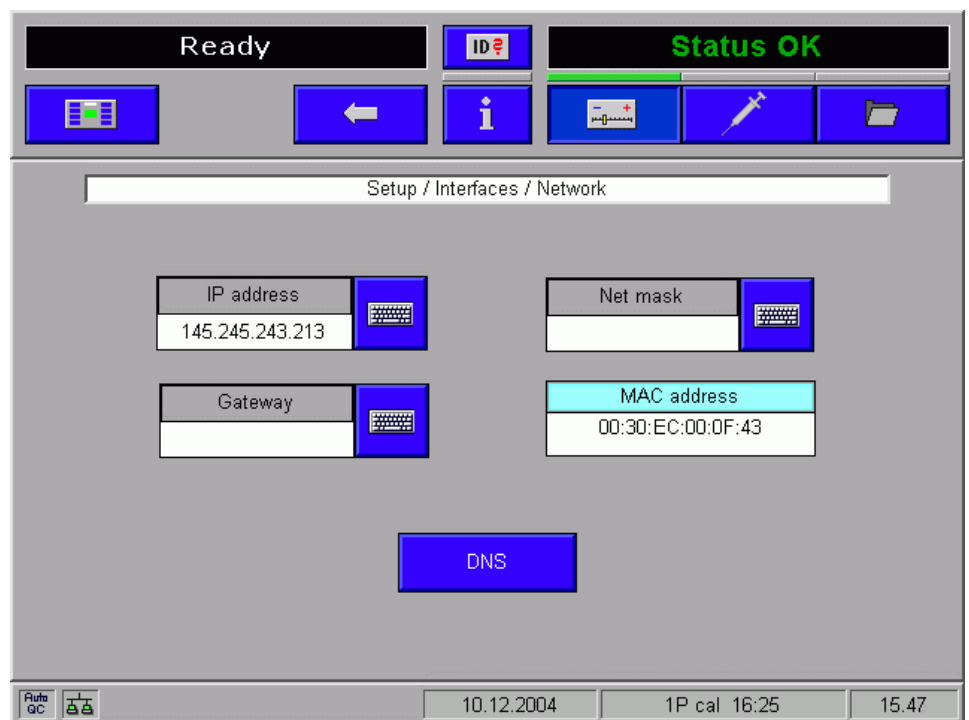


Press the keyboard button next to IP address.

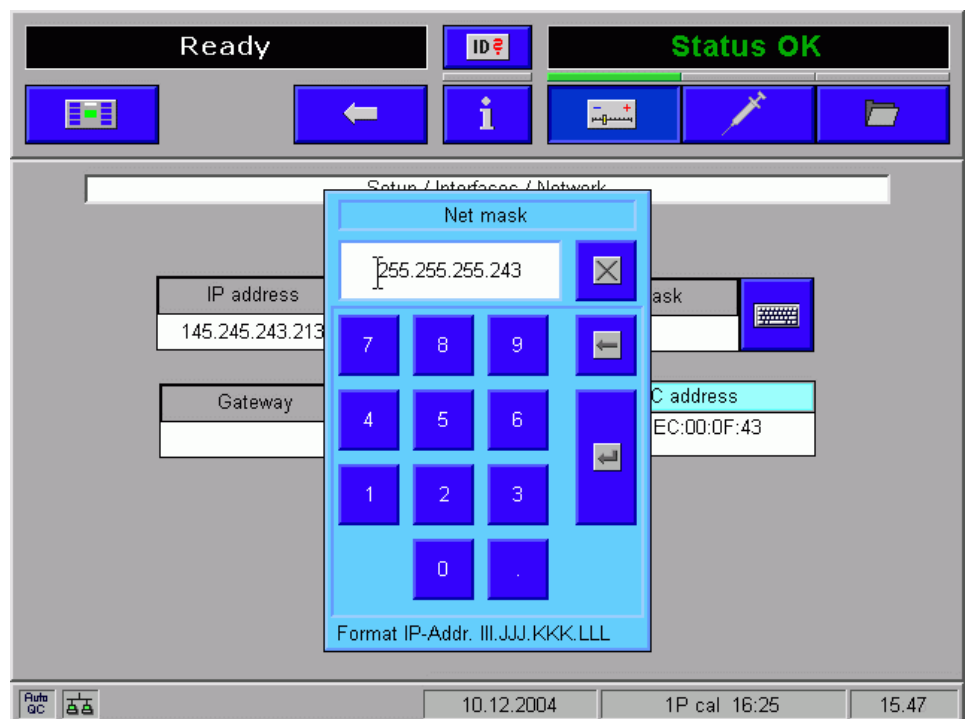
*Hint: The MAC address is displayed there, which might be useful for networks being generally managed using DHCP.*




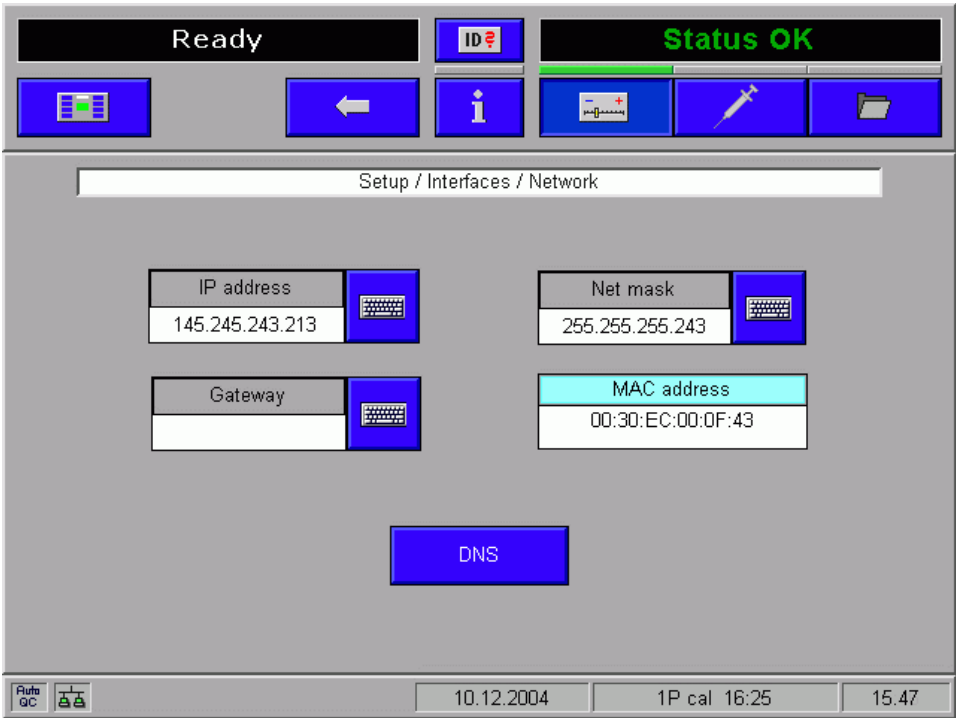
Type in the IP address as given by hospital IT and press the  button.



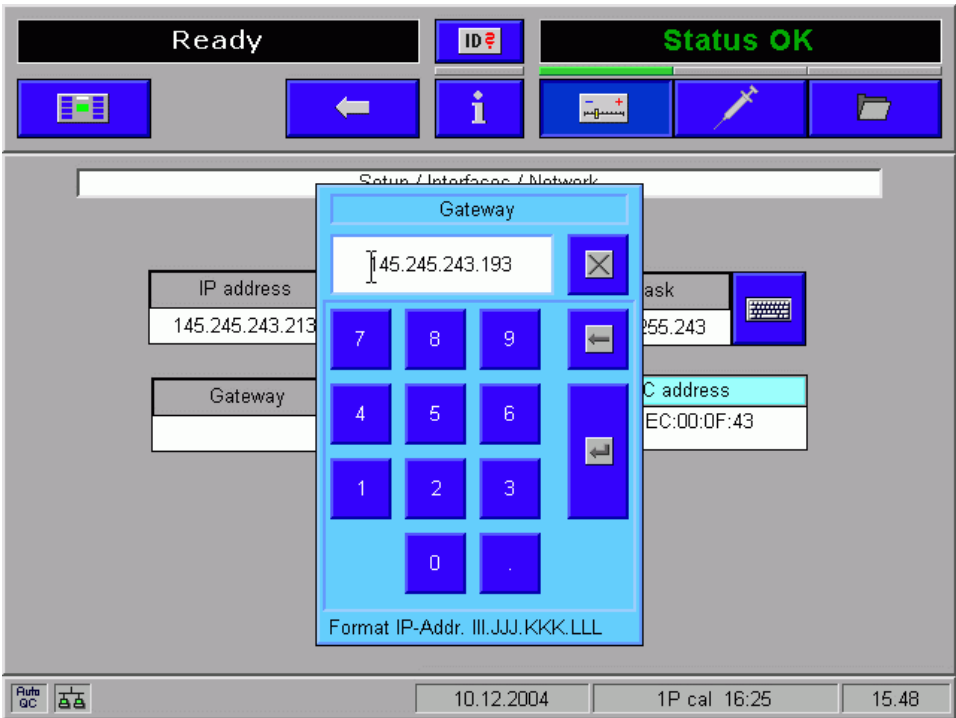
Press the keyboard button next to Net mask.



Type in the sub-net mask as given by hospital IT and press the  button.



Press the keyboard button next to Gateway.



Type in the gateway as given by hospital IT and press the  button.

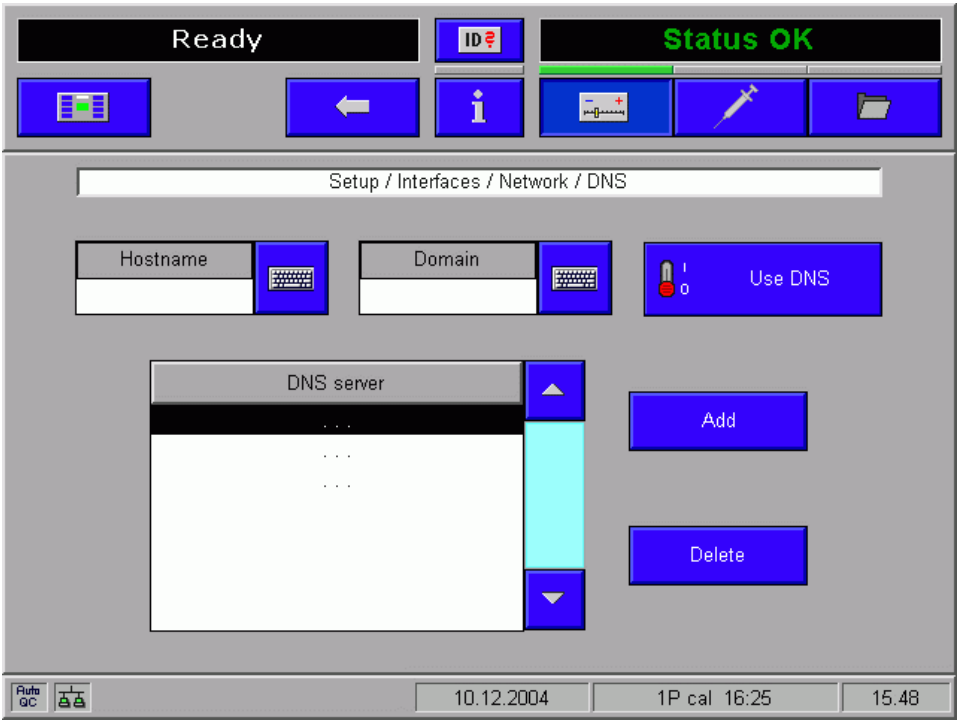
The screenshot shows a graphical user interface for network configuration. At the top, there is a status bar with 'Ready' on the left, an 'ID?' button in the center, and 'Status OK' on the right. Below this is a row of icons: a monitor, a left arrow, an information 'i' icon, a document with a plus sign, a syringe, and a folder. A breadcrumb trail 'Setup / Interfaces / Network' is displayed. The main area contains four input fields: 'IP address' with the value '145.245.243.213', 'Net mask' with '255.255.255.243', 'Gateway' with '145.245.243.193', and 'MAC address' with '00:30:EC:00:0F:43'. Each field has a keyboard icon to its right. A blue 'DNS' button is centered below these fields. The bottom status bar includes 'Auto GC' with a balance scale icon, the date '10.12.2004', '1P cal 16:25', and the time '15.47'.

By pressing the DNS button you can enter the area to enter the domain name service data. By using DNS, it is possible to use the host name of the ASTM recipient host alternatively to its IP address.

---

**Note:** The *cobas b 221 system/Roche OMNI S system* IP address has to be a fixed IP address!

---



In case you want to use DNS, by pressing the referring buttons please enter the data given by hospital IT here. Please remember to switch on "Use DNS" in this case.

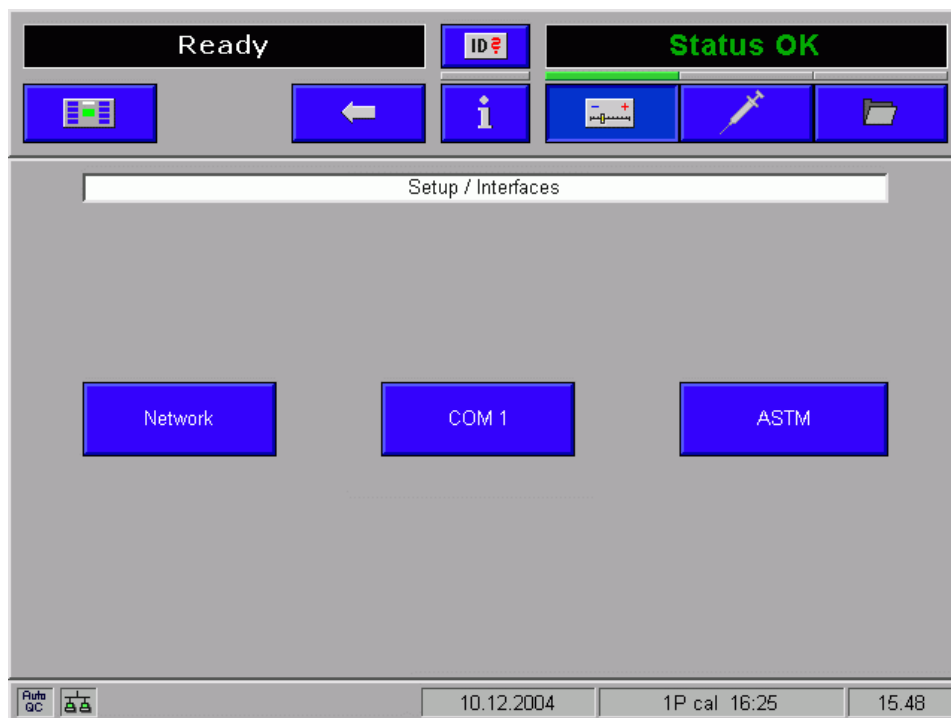
To complete and apply your network settings, press the **one level back** button until the screen below is shown again.



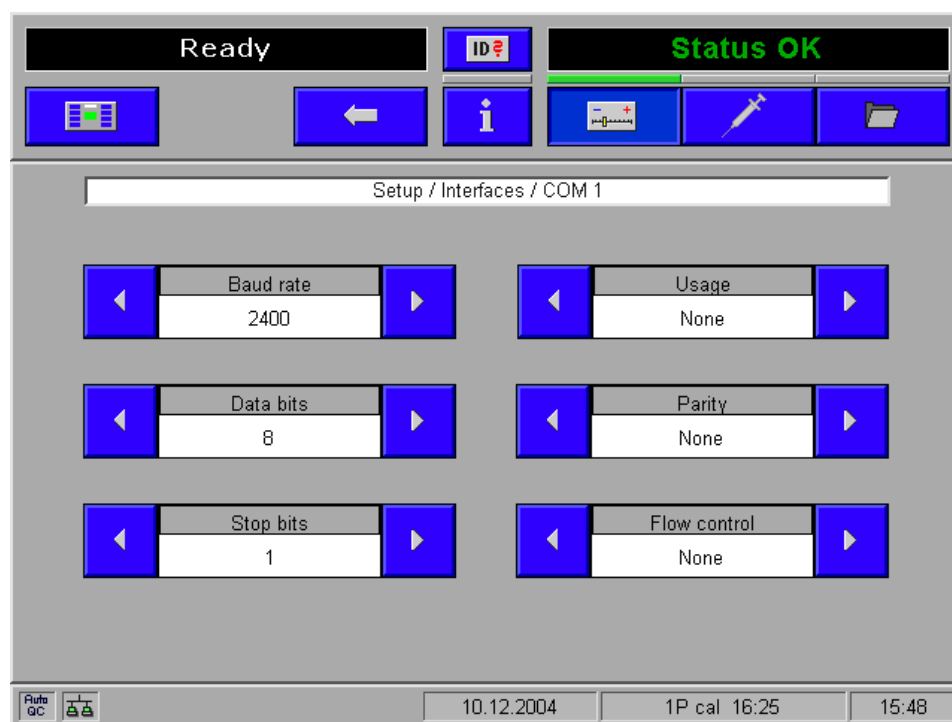


### 6.1.3 Serial Settings

Make sure, that the instrument's COM 1 serial port (on the instrument's rear) has been connected to a PC or terminal server using a 9-pin serial cable (null modem cable).



Press the COM 1 button.



Press the arrow button next to Usage until ASTM is shown.

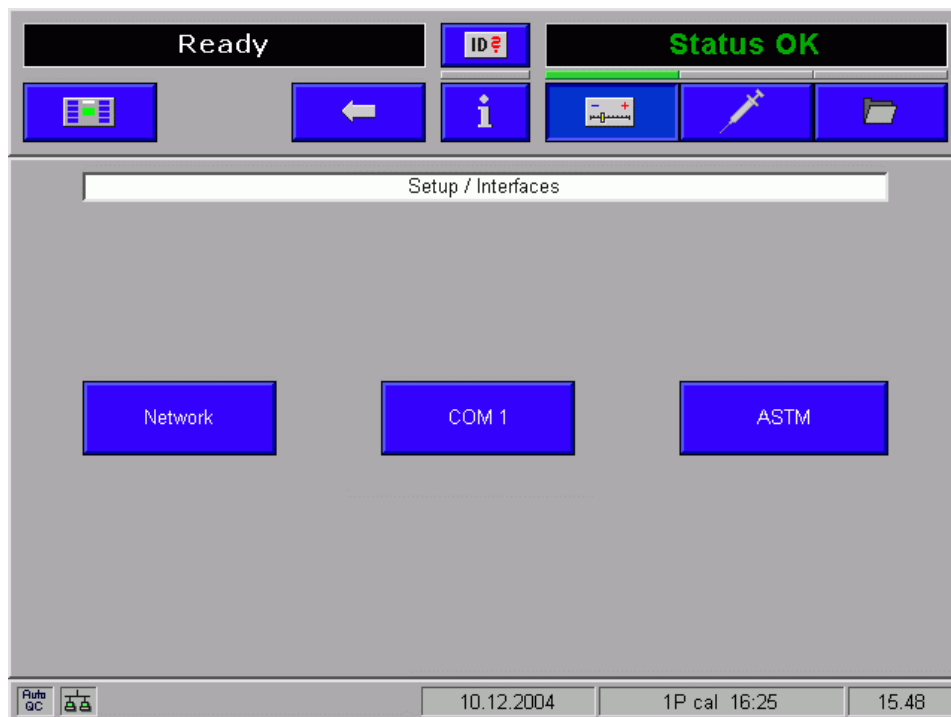


Make sure to set **Baud rate**, **Data bits**, **Stop bits**, **Parity** and **Flow control** identical to the current settings for the COM port used for the **cobas b 221 system/Roche OMNI S system** connection on the PC or terminal server.

To complete and apply the settings, press the **one level back** button.

### 6.1.4 ASTM Settings

*Note: In case the connection is going to be established via COM port the references to network connection (e.g. ASTM host IP address and port) can be ignored.*




Press the ASTM button.



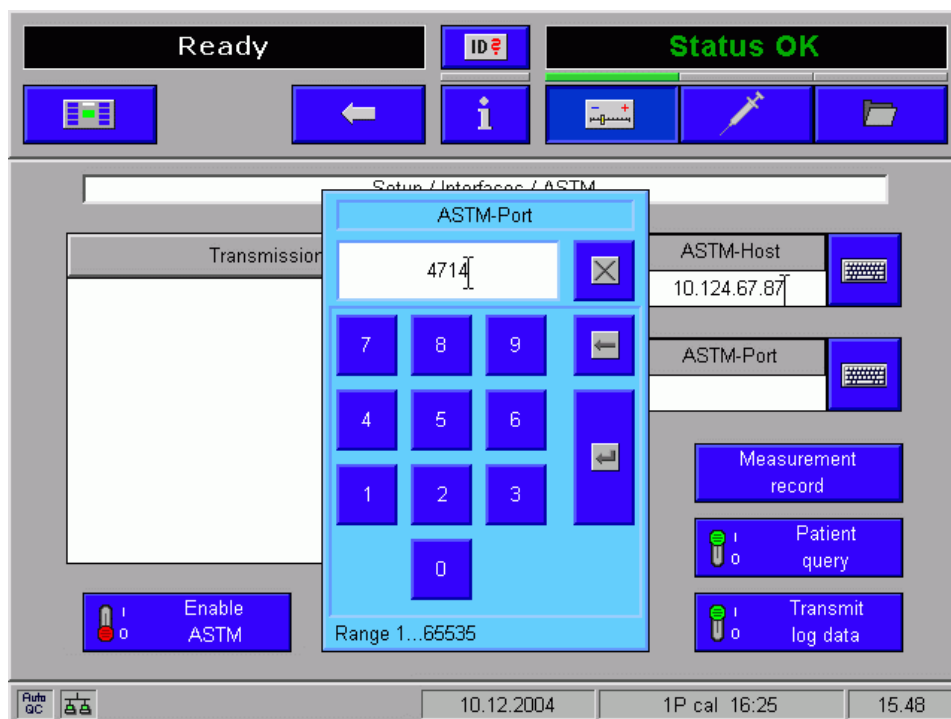
Press the keyboard button next to ASTM-Host.




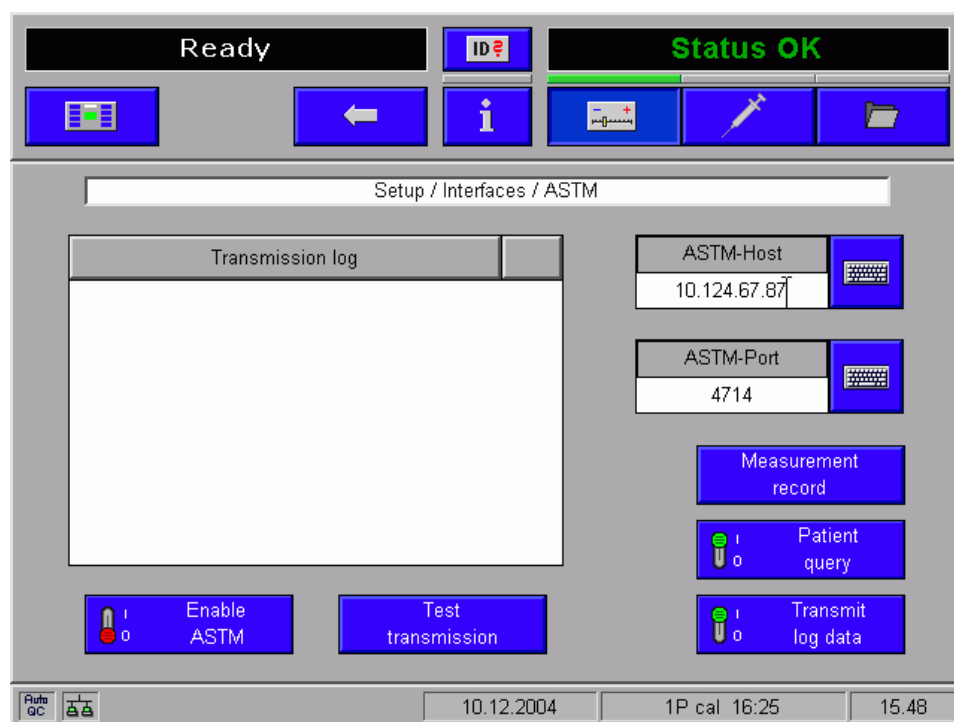
Type in the ASTM host PC IP address or host name (in case you are using DNS) as given by hospital IT and press the  button.



Press the keyboard button next to ASTM-Port.



Type in the ASTM host IP port as given by hospital IT and press the  button.

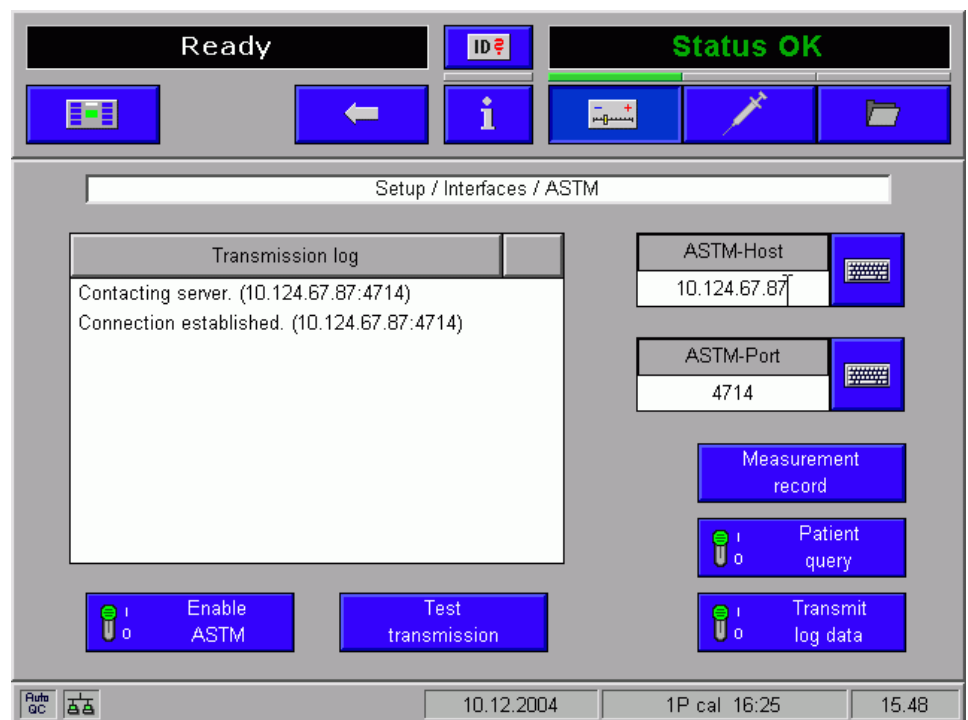


Switch ON the Enable ASTM switch. The **cobas b 221 system/Roche OMNI S system** will then try to contact the specified IP port on the specified PC and will display the result of this connection attempt.

*Note: From this point on, the cobas b 221 system/Roche OMNI S system will send the specified data streams to the set up recipient.*

*In case the Enable ASTM switch only is activated, only measurement, QC and calibration messages will be transmitted.*

*In case the connection is down (e.g. network problems or recipient down), the instrument will attempt a re-connection every time there is data to transmit.*



Using the **Patient query** switch you can set the instrument to send a query for patient demographics when a patient ID is entered during measurement. In case there is an active ASTM connection over TCP/IP patient query will be done only via this connection. Patient query over serial connection will be done only in case there is no active TCP/IP ASTM connection. Patient query over the OMNILINK connection will be done only in case there is no active ASTM connection (TCP/IP or serial).

Using the **Transmit log data** switch the transmission of maintenance and error messages can be activated.

After pressing the **Test transmission** button the instrument will attempt to send an empty (Header Record and Message Terminator Record only) to the host.

Press the **measurement record** button to select the data for transmission in measurement messages.



You can select a line by directly pressing it or using the arrow keys and the Toggle button to select/deselect it for transmission.

Make sure to press the Setup Home button to apply your settings.

## 6.2 Resending of Results

To allow for resending of data from the database, **mark** the measurement, QC or calibration records to be resent and press the **Export** button. Press the keyboard button next to Format, select ASTM and press the Enter button. Pressing the Start button starts the sending of the data.

**NOTE:** Make sure to mark the desired records. In case NO records are marked, ALL records will be resent.



### 6.3 Table and Order of Transmitted Results

The table below lists all values which are transmitted (if selected) 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.
PO2	2	
PCO2	3	
Hct	4	
Na	5	
K	6	
Ca	7	
Cl	8	
tHb	9	
SO2	10	
O2Hb	11	
COHb	12	
MethHb	13	
HHb	14	
Bili	15	
Glu	16	
Lac	17	
Urea	18	Whether Urea or BUN is transmitted in this place depends on which is set as measured parameter.
Baro	19	
H+	20	
cHCO3	21	
CtCO2(P)	22	

Name	Order	Remark
BE	23	
BE(act)	24	
BEecf	25	
BB	26	
SO2(c)	27	
P50	28	
FO2Hb	29	
ctO2	30	
ctCO2(B)	31	
pHst	32	
cHCO3st	33	
PAO2	34	
AaDO2	35	
a/AO2	36	
avDO2	37	
RI	38	
Qs/Qt	39	
OER	40	
niCa	41	
AG	42	
pHt	43	
cHt	44	
PCO2t	45	
PO2t	46	
PAO2t	47	
AaDO2t	48	
a/AO2t	49	
RIt	50	

Name	Order	Remark
Hct(c)	51	
MCHC	52	
Osm	53	
BO2	54	
BUN	55	
Qt	56	
PFIndex	57	
ALLEN test	58	
Pat.Temp	59	
R	60	
FIO2	61	
tHb(e)	62	
Hb Factor	63	
24h Urine	64	
Vent Mode	65	
VT	66	
MV	67	
PIP	68	
Ti	69	
Te	70	
SRATE	71	
ARATE	72	
PEEP	73	
MAP	74	
Flow	75	
Age (A/F)	76	
Date drawn	77	
Time drawn	78	

Name	Order	Remark
Date changed	79	
Time changed	80	
Department	81	
Accepted by	82	
Billing code	83	
Remark	84	

## 6.4 Table of Measured Parameters

The table below lists all possible measured values that are available on the **cobas b 221** system/Roche OMNI S system and can be transmitted to the host system.

Name	ID
pH	1
H+	2
PO2	3
PCO2	4
Hct	5
Na	6
K	7
Ca	8
Cl	9
tHb	10
SO2	11
O2Hb	12
COHb	13
MetHb	14
HHb	16
Bili	17
Glu	18

Lac	19
Urea	24
BUN	25
Baro	31

## 6.5 Table of Calculated Parameters

The table below lists all possible calculated values that are available on the **cobas b 221 system/Roche OMNI S system** and can be transmitted to the host system. For explanations, see the **cobas b 221 system** Instructions for Use, page A-97, “Parameters and calculations”.

Name	ID
H+	50
cHCO <sub>3</sub>	51
ctCO <sub>2</sub> (P)	52
BE	53
BE(act)	54
BEecf	55
BB	56
SO <sub>2</sub> (c)	58
P50	59
ctO <sub>2</sub>	60
ctCO <sub>2</sub> (B)	61
pHst	62
cHCO <sub>3</sub> st	63
PAO <sub>2</sub>	64
AaDO <sub>2</sub>	65
a/AO <sub>2</sub>	66
avDO <sub>2</sub>	67
RI	68
Qs/Qt	69
niCa	70

Name	ID
AG	71
pHt	72
cHt	73
PCO2t	74
PO2t	75
PAO2t	76
AaDO2t	77
a/AO2t	78
Rit	79
Hct (c)	80
MCHC	81
Osm	82
OER	83
BO2	84
BUN	85
Qt	86
C	87
PFIndex	88
FO2Hb	89

## 6.6 Table of Input Parameters

The table below lists all input parameters that are available on the **cobas b 221 system/Roche OMNI S system** and can be transmitted to the host system. For explanations and availability, see the **cobas b 221 system Instructions for Use**, page B-58, “Parameters”.

Name	ID	Transmitted in Record Type
Practice Patient ID	100	Patient Information Record
Patient ID	101	Patient Information Record
Insurance Number	102	Patient Information Record

Name	ID	Transmitted in Record Type
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 (A/F)	110	Patient Information Record
Sex	111	Patient Information Record
Ethnic Origin	112	Patient Information Record
Address	113	Patient Information Record
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

Name	ID	Transmitted in Record Type
Patient Language	131	Patient Information Record
Hospital Service	132	Patient Information Record
Hospital Institute	133	Patient Information Record
Dosage Category	134	Patient Information Record
Measurement Time	135	Header Record
Measurement Date	136	Header Record
Time Changed	137	Result Record
Date Changed	138	Result Record
Operator ID	139	Part of first Result Record
Remark	140	Result Record for measurement, Comment Record for QC
Specimen ID	141	Test Order Record
Samples	142	Not transmitted
Order ID	143	Test Order Record
Acceptor	144	Result Record
Date Drawn	145	Result Record
Time Drawn	146	Result Record
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 test	152	Result Record
Container	153	Test Order Record
Pat.Temp.	155	Result Record
R	157	Result Record
FIO2	158	Result Record
24h Urine	159	Result Record
Vent Mode	160	Result Record



Name	ID	Transmitted in Record Type
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
tHb(e)	171	Result Record
HbF	172	Result Record
Billing code	173	Result Record
Department	174	Result Record

## 6.7 Table of Sample Types & Blood Types

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

