European BD MAX

LIS Vendor Interface

1. Purpose

This document describes the configuration of the interface between an LIS and the BD MAX instrument. This document describes the communication between the BD MAX and an LIS and also the GUI configuration screen at the BD MAX instrument.

2. Definitions

ASTM – American Society for Testing and Materials; Committee responsible for publishing specification on communication between lab instruments and lab computer systems.

ASTM E_1381 – Protocol published by ASTM describing low-level data exchange.

ASTM E_1394 – Protocol published by ASTM describing the logical level formatting of patient and test data.

Confirmed Positive – This is a positive result that has been confirmed as a positive by the user on the Results, Run Details, PCR Analysis screen. This status is only used in the LIS Result record.

Date/Time – All times will be represented in local time unless otherwise specified

Invalid characters – The following list of characters will not be accepted at the BD MAX. " * ? [ ] ! # | ' & < > { } ~ ^ \

LIS – Laboratory Information System; Computer system present in most microbiology labs responsible for collecting patient and test data.

LIS Interface Library – Common module responsible for implementing communication protocols. This module is used by both the BD instruments and the EpiCenter for LIS communication.

Instrument Positive – This is the positive result that is determined by the instrument. It is a preliminary positive until it is confirmed as a positive, if option enabled by the user on the Results, Run Details, PCR Analysis screen. This status is only used in the LIS Result record.

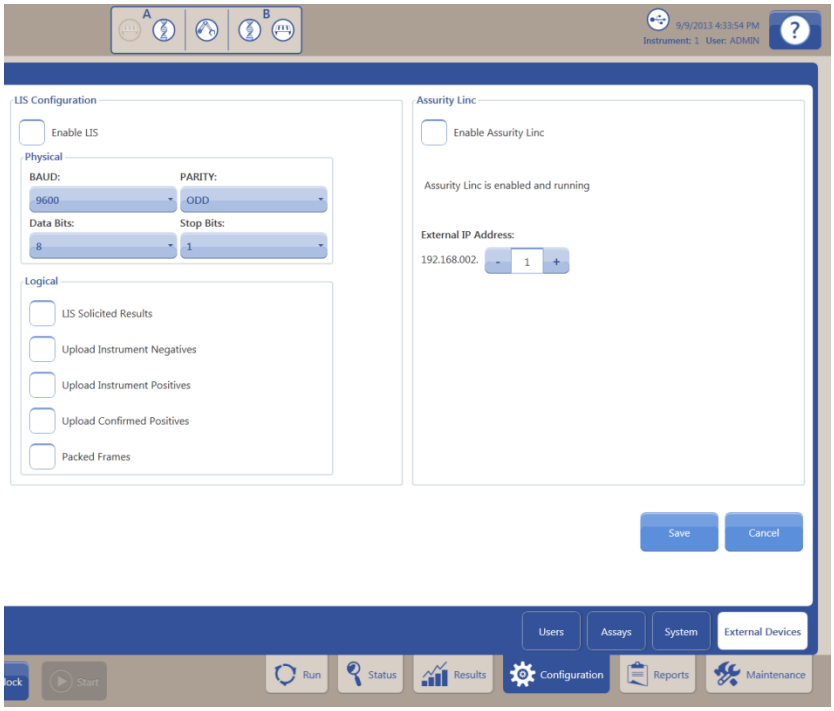
Valid Characters – The following characters are acceptable for entry at the BD MAX instrument. A – Z, a – z, 0 – 9, ; : , . / @ $ % ( ) _ + - ` =

3. BD LIS Interface

The LIS Connection is a transfer of data between our System and the Laboratory Information System (LIS). Between them there is the LIS- Driver (middleware- program) that captures the results from our device and converts it in a format that the LIS- System can handle. **This is not only an exchange of data. It is a real serial communication between two parties.** A LIS connection is a very simple way to transfer data. The data size is very small and it does not use the clinical network, so no need to install anti-virus or additional software.

If the LIS is enabled, the application will create an LIS interface thread at start up. The BD MAX will communicate results to the LIS based on the user selected configuration options. The protocols and specifications for exchanging data are described in this and subsequent sections.

The BD MAX LIS Configuration Screen lets the user specify the configurable behavior of the LIS interface. To navigate to the BD MAX LIS Configuration Screen, select the Configuration Tab then the External Devices Tab. The LIS Configuration options are in the middle of the External Devices Tab.



4. LIS Communication

When the BD MAX completes a run, if the LIS is enabled and if the LIS Solicited Results is enabled (checked), results will be send only when the LIS requests results and if results are within the specified date/time range of the request. The default setting is LIS Solicited Result enabled.

If the LIS Solicited Results is disabled (unchecked) then the configuration settings for the unsolicited mode result upload will be become available. If the user has configured the LIS to upload instrument negative results, the negative results will be uploaded to the LIS. If the user has configured the LIS to upload instrument positive results, the instrument positive results will be uploaded to the LIS. If the user does not desire to have the instrument

positive results sent to the LIS, a feature will be provided that gives the user the ability to confirm the positive result and then send the confirmed positive result to the LIS. The user will be able to confirm the positive result on the Results, Run Details, Plotting screen. If the user has configured the LIS to upload confirmed positive results in unsolicited mode, the confirmed positive results will be sent to the LIS as soon as possible.

Note: To have the uploading of negative and positive results and confirmed positives available with Open System Testing, the Result Logic needs to be enable and programmed.

Once a result has been successfully sent to the LIS in the unsolicited mode of operation, it will not be resent to the LIS.

Note: Individual results can be manually re-transmit to LIS, using the Re-transmit LIS button in the Run Details tab.

The result information that will be sent to the LIS is based on the date range specified in the query and the types of results that have been configured to be sent to the LIS (instrument negative, instrument positive, and/or confirmed positives). When configured to send a result record to the LIS, the instrument will send a result message to the LIS containing H/P/O/R/L records. **For a result to be sent to the LIS, the test must have an Accession.**

Sending of the types of results for solicited or unsolicited mode can be enabled or disabled via the Configuration tab/External Device tab.

4.1 Communication Protocols

The American Society for Testing and Materials (ASTM) has published standards for how information should be exchanged between a clinical instrument and lab computer system. BD has implemented communication software to adhere to these specifications.

4.1.1 Logical protocol (ASTM E_1394)

ASTM E_1394 is the publication that outlines the **logical formatting** of medical information. This is the logical protocol BD uses to read/write data exchanged with the LIS. The ASTM E_1394 publication should be referred to for implementation details.

The Logical protocol describes where to place individual pieces of information into a record string and how to combine the record strings into a properly formatted message. The combination of logically grouped records is called a data packet. DATA PACKETS are composed of **RECORDS**, which contains the data that is transferred between an LIS and Instrument. The data within the RECORD is separated into **FIELDS** by **DELIMITERS** (**|**). Within a field we can have a caret (^) that can split the field in a subfield (component) for additional information. RECORDS contain logical subdivisions of information identifying the sender of the message, patient, test order, test results, requests for information, comments and end of the data packet.

A **letter in the first field of the record** always identifies the **record type**.

H (Header Record: Sendername)

P (Patient Record: Patient data)

O (Order Record: Accession No)

R (Result Record: Result data)

L (Termination Record: End of the Record)

H|\^&|||Becton Dickinson|||||||V1.0|20120802113802

P|1|1110815|

O|1|MR210014||^^^BDMAX_AND

R|1|^^^AND|INST_POSITIVE|||||P|||20120802095229||BDMAX_AND^^^1^25-B6-B-TOP-5^^^MRSA|^FALSE

L|1|N

4.1.2 Physical protocol (ASTM E_1381)

ASTM E_1381 is the publication that outlines the **physical communication** of medical information. This is the physical protocol BD uses to read/write data exchanged with the LIS. A later section in this document discusses any deviations from that specification.

4.1.2.1 Unpacked/packed Frames

BD interprets the ASTM E_1381 specification to imply that an intermediate frame of a message should be packed to be 240 characters in length. The only frame that should be less than 240 bytes in size is the last frame of a message.

However BD has had feedback from several LIS vendors who interpreted the ASTM E_1381 specification differently. These vendors have requested that the BD LIS interface be able to send and receive frames that contain only a single logical record. (i.e. Header, Result and Terminator records all are sent in separate frames). This implies that most frames are less than 240 bytes in length. However it is still possible that a single logical record could be longer than the 240 bytes limit for a frame. In this case a single logical record is sent in several consecutive intermediate frames. All but the last frame is packed to 240 bytes and the last frame containing that logical record is less than 240 bytes. If selected (packed) BD MAX will send blocks (and also expect blocks). If unselected (unpacked) the BD MAX will send frame by frame and after each line, it will expect an ACK from the listener.

The BD LIS interface is configurable to send either packed frames or unpacked frames, which contain a single record per frame. This setting need to be discuss with the LIS vendor

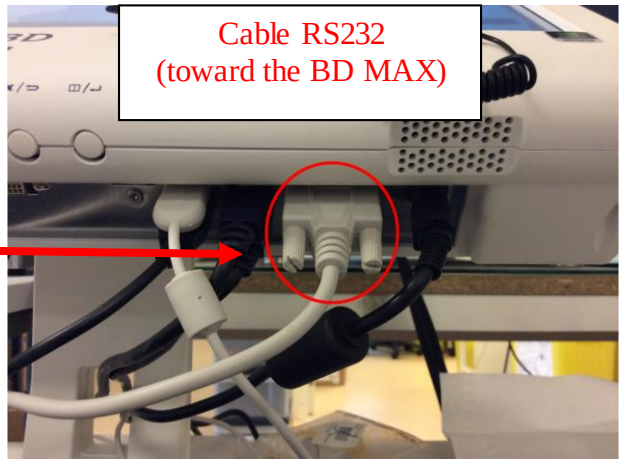
4.2 Physical Cable Interface

The **only possibility** to make a LIS connection is via **RS232 COM- Port.** With BD MAX it **must** be **COM 1**, no possibility to use another port. All AIO have the serial port.


Male RS232

Cable Ethernet RJ45 (toward LIS)

Cable RS232 (toward the BD MAX)



Note : The additional hardware devices described are not provided by BD and haven't been tested internally. USB to COM – Port- Adapter or a MOXA box can be required.

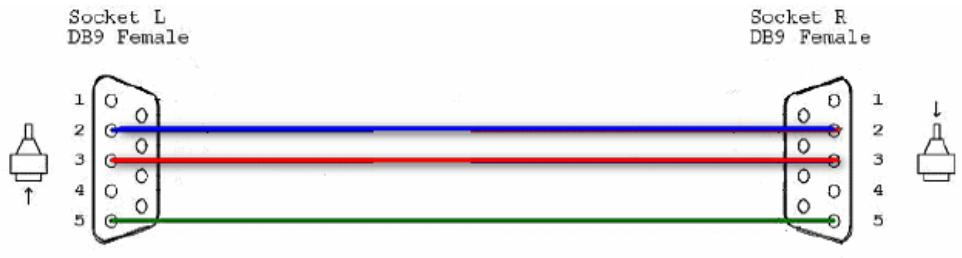
4.3 SERIAL DATA Transmission

Serial communication using RS-232 requires that you specify four parameters: the **baud rate** of the transmission, the number of **data bits** encoding a character, the sense of the optional **parity** bit, and the number of **stop bits**.

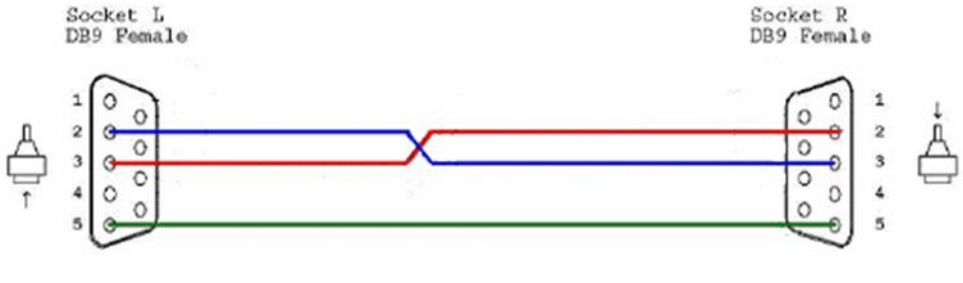
The above connection schema is often confused or misinterpreted when discussing an LIS interface connection. Though the physical communication between the LIS and Instrument is via an RS-232 serial interface, the physical cable used is a **NULL modem serial cable (female-to-female**), not a straight-through male-to-female cable. NULL modem serial cables are used to connect DTE-to-DTE devices (PC-to-PC) as in an LIS connection as seen below.

Null Modem Cable

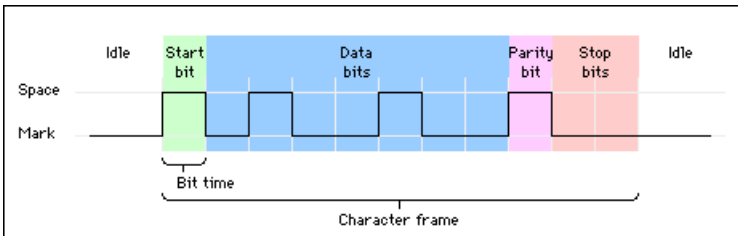
For all devices the COM- Port has the same configuration. If the devices send and listen at the same port, information cannot transfer from A to B.



Data lines must be **crossing** and the transmittion line need to be connected to a listener line. This „**cross**ing **over**" of the lines is made by a **Null Modem Cable** (function like a switch).



Each transmitted character is packaged in a character frame that consists of a single start bit followed by the data bits, the optional parity bit, and the stop bit or bits. A typical character frame encoding the letter "m" is shown here.



5. Message Content

The following sections describe which fields are exchanged between the BD MAX and the LIS.

5.1 Field List

This section lists all of the fields by name BD MAX can exchange with the LIS.

Each field is displayed with its default mapping in the ASTM E_1394 records. This position consists of a record type (Header, Result, Query, or Terminator), a field delimiter counter, repeat delimiter counter, and component delimiter counter. The fields are grouped according to the ASTM E_1394 record type to which they are mapped.

The field list also indicates if that field is defaulted as an upload (U) or download (D) field, or both (U/D). The first two fields of every record include the Record Type indicator and a record index value. These fields are considered part of every record but are not listed in these tables.

For example "Sender Name"

ASTM Pos.: H (Record Type), 5 (Field Position), 1 (Repetition No), 1 (Component No)

Direction: U/D (Upload to LIS/ Download from LIS)

It will be counted from the start of the line

H|\^&| | |Becton Dickinson| | | | | | | |V1.0 |20151120171114 1|2 |3 |4|Sender name |6|7|8|9|10|11|12|Version No|Message D/T

The following section describes these fields in more detail, including the expected values for each field.

Header Record Field Name	ASTM Pos.	Direction
Sender Name (Becton Dickinson)	H, 5, 1, 1	U/D
Version Number	H, 13, 1, 1	U/D
Message Date/Time(YYYYMMDDHHMMSS)	H 14, 1, 1	U/D

Header Fields

Delimiter Fields (H, 2, 1, 1) – These single characters can be used to process the remainder of the message. These characters denote the field, repeat, component and escape delimiters as described in the ASTM E_1394 specification. These fields are defaulted to "|", "\", "^", and "&" respectively, as shown above.

Sender Name (H, 5, 1, 1) – Messages coming from a Becton Dickinson instrument have the BD identifier in this field as shown above.

Version Number (H, 13, 1, 1) – This version number represents the version of the LIS interface used for communications. For the BD MAX instrument, the version number will begin with Vs1.00.

Message Date/Time (H, 14, 1, 1) – BD includes the current time and date when constructing his message, formatted as described in the ASTM E_1394 specification in section 6.6.2 (YYYYMMDDHHMMSS).

H|\^&|||Becton Dickinson|||||||V1.0|20111110091907

Patient Record Field Name	ASTM Pos.	Direction
Patient ID	P, 4, 1, 1	U/D

Patient Record Field Name

Patient ID (P, 4, 1, 1) – Identifier that uniquely identifies a patient. This field can be up to 20 characters long. This field will be send only if Patient ID field is activated on the Worklist. This field is optional.

P|1| |PatId123

Note: Not fixed to PatId123. This can be any acceptable characters.

Order Record Field Name	ASTM Pos.	Direction
Accession Number	O, 3, 1, 1	U/D
Test ID (BDMAX_AND)	O, 5, 1, 4	U/D

Order Record Field Name

Accession Number (O, 3, 1, 1) – The unique alphanumeric string that identifies a specimen. This field can be up to 20 characters long. When connected to LIS the accession number will have to be activated on the Worklist. This is a required field for result uploaded to the LIS.

Test ID (O, 5, 1, 4) – The unique string that identifies the BD instrument type and test type. In the case of the BD MAX instrument, this will always be BDMAX_AND.

O|1|23878||^^^BDMAX_AND

Result Record Field Name	ASTM Pos.	Direction
Result ID Code (**AND)**	R, 3, 1, 4	U

Result Record Field Name	ASTM Pos.	Direction
Test Status	R, 4, 1, 1	U
User Result Identifier	R, 4, 1, 2	U
Preliminary/Final Status (P)	R, 9, 1, 1	U
Test Start Date Time	R, 12, 1, 1	U
Instrument Type(BDMAX)	R, 14, 1, 1	U
Instrument Number (1-99)	R, 14, 1, 4	U
Instrument Position (specimen location)	R, 14, 1, 5	U
Test/Assay Name	R, 14, 1, 8	U
Confirmed Positive indicator	R, 15, 1, 2	U

Result Record Field Name

Result ID Code (R, 3, 1, 4) – This is a BD defined code that indicates the type of information being exchanged in the result record. The BD MAX transmits a "**AND**" (Amplification and Detection) as the Result ID Code.

Test Status (R, 4, 1, 1) – For the BD MAX instrument tests, the status code is one of the pre-defined values set by the customer. This field is filled for all test results. The possible values are:

- INST_POSITIVE : upload all positive
- INST_NEGATIVE: upload all negative
- CONFIRMED_POSITIVE: upload confirmed positive

R|1|^^^AND|INST_NEGATIVE|||||P|||20140823132809||BDMAX_AND^^^1^62-A4-A-BOT-10^^^SA|^FALSE

Note : When the "confirmed positives" setting is not enable, strings for inst_negative and ins_positive will always include a ^FALSE after the test results.

User Result Identifier (R, 4, 1, 2) – A user defined result string. This field is optional and rarely seen..

Preliminary/Final Status (R, 9, 1, 1) – This field contains a "P" to indicate the results should be considered Preliminary Final Results for the INST_POSITIVE and INST_NEGATIVE test results. This shall always be "P".

Start Date/Time (R, 12, 1, 1) – This is the date and time that the test was first started or entered into an instrument. This field is formatted as described in the ASTM E_1394 specification. (YYYYMMDDHHMMSS format).

Instrument Type (R, 14, 1, 1) – This field indicates which BD instrument produced the result. This field contains the value, "BDMAX".

Machine Instrument Number (R, 14, 1, 4) – This is the user number assigned to the instrument that ran the test. This value can be between 1 and 99.

Location Information (R, 14, 1, 5) – Specimen location. This value indicates the position inside of the instrument where the test was performed.

Test/Assay name(R, 14, 1, 8) – For upload, this field correspond to the assay targets analytes (see table in annex). For UDP, analytes are based on the Results Logic settings. One string per target. The maximum length of the test name is 40 characters. Note that each analyte have a line number from 1,2,3… depending on the number of targets reported (R|1|, R|2|, R|3|…)

Confirmed Positive (R, 15, 1, 2) – When the "confirmed positives" setting is enable, this is the user set indication that the positive test has been "confirmed" as a positive.

R|1|^^^AND|INST_POSITIVE|||||P|||20111105075215||BDMAX_AND^^^1^982-B12-B-TOP-12^^^SA|^CONFIRMED POSITIVE

Terminator Record Field Name	ASTM Pos.	Direction
Termination Code (L|1|N)	L, 3, 1, 1	U/D

5.2 Result Codes for upload

Syntax for upload code (from MAX to LIS)

H|\^&|||Becton Dickinson|||||||V1.0|**Date-Time**

P|1||**Patient- ID**

O|1|**Accession-Number**||^^^TestID

R|1|^^^ResultIDCode |**TestStatus**|||||**Preliminary/Final**|||**Date-Time**||InstrumentType^^^
N°instrument^Position of Sample^^^**Test Name**|^*ConfirmationTRUE/FALSE*

L|1|N

Example with BD MAX StaphSR :

Upload all negatives

H|\^&|||Becton Dickinson|||||||V1.0|**20140823151055**

P|1||**PatId123**

O|1|**AB99990008**||^^^BDMAX_AND

R|1|^^^AND|**INST_NEGATIVE**|||||**P**|||**20140823132809**||BDMAX_AND^^^1^62-A4-A-BOT-10^^^**SA**|^*FALSE*

R|2|^^^AND|**INST_NEGATIVE**|||||**P**|||**20140823132809**||BDMAX_AND^^^1^62-A4-A-BOT-10^^^**MRSA**|^*FALSE*

L|1|N

Note : When the "confirmed positives" setting is **not enable**, strings for inst_negative and ins_positive will always include a FALSE after the test results.

Upload all positives :

H|\^&|||Becton Dickinson|||||||V1.0|20140823151055

P|1||PatId123

O|1|AB99990008||^^^BDMAX_AND

R|1|^^^AND|INST_POSITIVE|||||P|||20140823132809||BDMAX_AND^^^1^62-A4-A-BOT-10^^^SA|^*FALSE*

R|2|^^^AND|INST_POSTIVE|||||P|||20140823132809||BDMAX_AND^^^1^62-A4-A-BOT-10^^^MRSA|^*FALSE*

L|1|N

Note : When the "confirmed positives" setting is **not enable**, strings for inst_positive and ins_positive will always include a FALSE after the test results.

Upload Confirmed positive:

H|\^&|||Becton Dickinson|||||||V1.0|20140823151055

P|1||PatId123

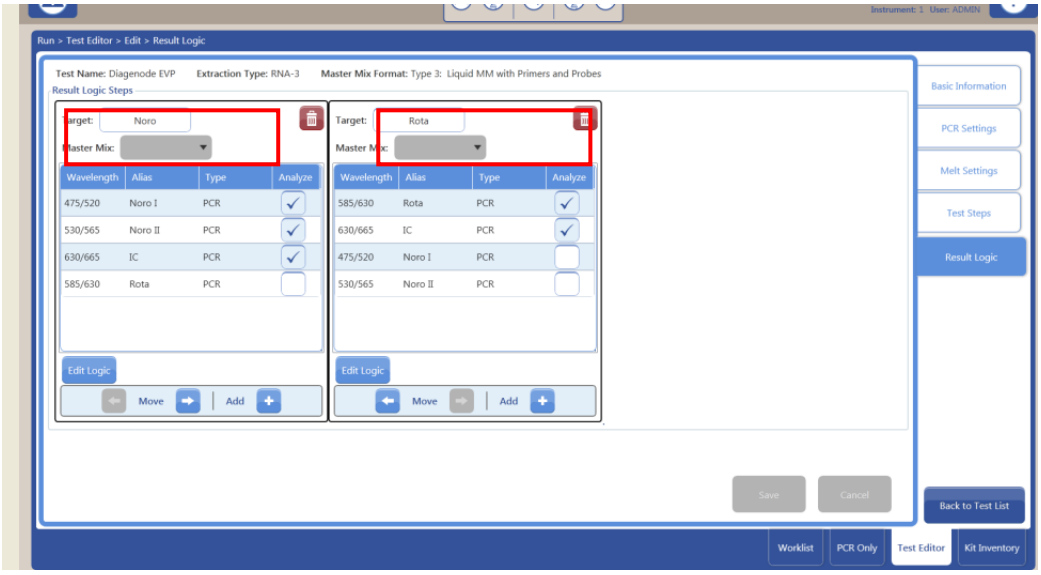
O|1|AB99990008||^^^BDMAX_AND

R|1|^^^AND|INST_POSITIVE|||||P|||20111105075215||BDMAX_AND^^^1^982-B12-B-TOP-12^^^SA|^CONFIRMED POSITIVE

R|2|^^^AND|INST_POSITIVE|||||P|||20111105075215||BDMAX_AND^^^1^982-B12-B-TOP-12^^^MRSA|^CONFIRMED POSITIVE

5.3 Open System configuration

Result logic must be configured so that results can be sent to the LIS. Assay and target(s) name(s) are chosen by the user. For upload code, the **target alias** chosen by the user will be used.



Upload all negatives

H|\^&|||Becton Dickinson|||||||V1.0|20140823151055

P|1||PatId123

O|1|AB99990008||^^^BDMAX_AND

R|1|^^^AND|INST_NEGATIVE|||||P|||20140823132809||BDMAX_AND^^^1^62-A4-A-BOT-10^^^Noro|^*FALSE*

R|2|^^^AND|INST_NEGATIVE|||||P|||20140823132809||BDMAX_AND^^^1^62-A4-A-BOT-10^^^Rota|^*FALSE*

L|1|N

Note: Results have to be present on the MAX, when setting up the connection for the first time allowed extra time to run few samples in order to get results.

5.4 Bi-directional connection

5.4.1 Order fields: Download of Patient information from LIS

The following information can be downloaded to the MAX from LIS and will be imported to the Worklist. Delimiter, Header and Patient record fields described below have the same position and ifnormation for both upload and download message codes. The Order ecord fields however have a different position. The Order record field "Test/Assay Name" contains a different information than upload and can only be only used with download (O16,1,1).

Delimiter Fields (H, 2, 1, 1) – These single characters can be used to process the remainder of the message. These characters denote the field, repeat, component and escape delimiters as described in the ASTM E_1394 specification. These fields are defaulted to "|", "\", "^", and "&" respectively, as shown above.

Header Record Field Name	ASTM Pos.	Direction
Message Date/Time	H 14, 1, 1	U/D

Header Fields

Message Date/Time (H, 14, 1, 1) – BD includes the current time and date when constructing his message, formatted as described in the ASTM E_1394 specification in section 6.6.2 (YYYYMMDDHHMMSS).

Patient Record Field Name	ASTM Pos.	Direction
Patient ID	P, 4, 1, 1	U/D

Patient Record Field Name

Patient ID (P, 4, 1, 1) – Identifier that uniquely identifies a patient. This field can be up to 20 characters long. This field will be send only if Patient ID field is activated on the Worklist. This field is optional.

P|1| |PatId123

Note: Not fixed to PatId123. This can be any acceptable characters.

Order Record Field Name	ASTM Pos.	Direction
Accession Number	O, 3, 1, 1	U/D
Test ID	O, 5, 1, 4	U/D
Test/Assay Name	O, 16, 1, 1	D

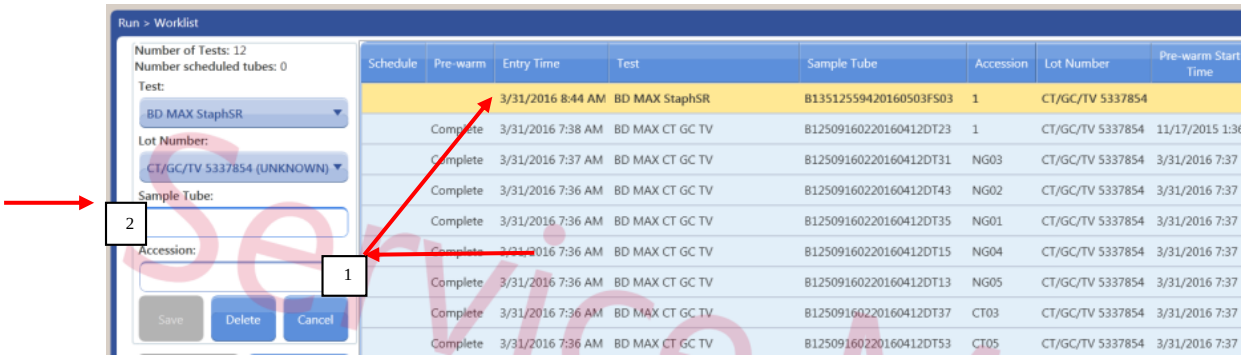
Order fields:

Accession Number (O, 3, 1, 2) – The unique alphanumeric string that identifies a specimen. This field can be up to 20 characters long. When connected to LIS the accession number will have to be activated on the Worklist. This is a required field for a result upload to the LIS.

Test ID (O, 5, 1, 4) – The unique string that identifies the BD instrument type and test type. In the case of the BD MAX instrument, this will always be BDMAX_AND.

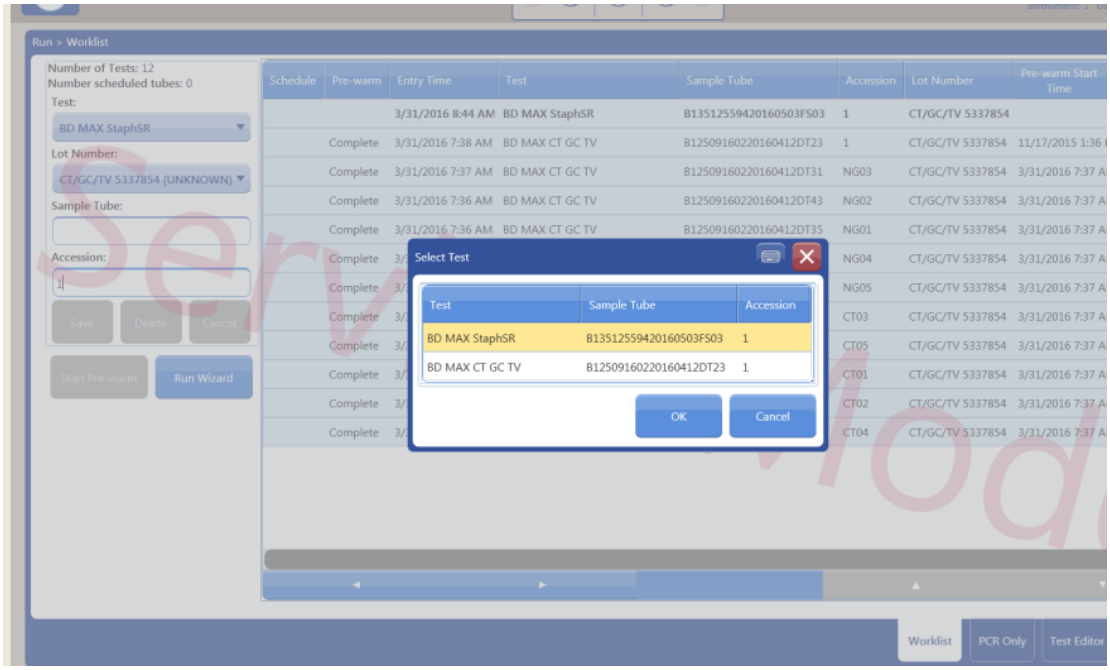
Test/assay name (O, 16, 1, 1): For download code, this name as to be the same as the ADF name. This is the Assay name from the BD MAX instrument. The maximum length of the test name is 40 characters.

Once the patient information **(Accession number, Assay name, Patient ID)** is imported in the Worklist, the user need to scan/enter the accession number **(in the 'Accession number' field(1))** to highlight in yellow the right tube. The SBT number can then be assigned to the patient **(in the 'Sample tube' field(2))**.



If more than one tube has the same accession number a window will open and prompt you to choose which test you want to select

Note: When setting up the connection for the first time, SBT need to be scan at first in order to allow the LIS to push patient information onto the MAX.



Note: It is possible to provide a holder for the barcode scanner and configure it so the scanner automatically triggers when you put something underneath it. This facilitates the creation of the worklist. See troubleshooting folder for more details

5.4.2.1 Result Codes for download

Syntax for download and queries (from LIS to MAX):

H|\^&|||||||||||**Date-Time**

P|1||**Patient- ID**

O|1|**Accession-Number**||^^^TestID||||||||||**Test/Assay-Name**

L|1|N

Example with BD MAX StaphSR :

H|\^&|||||||||||**20140527171834**

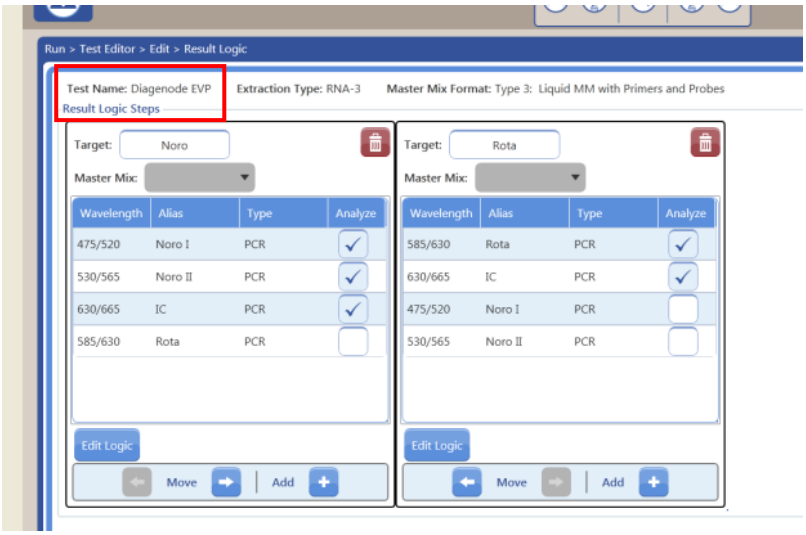
P|1||**PatId123**

O|1|**AB99990008**||^^^BDMAX_AND||||||||||**BD MAX StaphSR**

L|1|N

Test/Assay-Name : name of test as seen on the drop-down menu in Worklist (ADF and UDP)

5.4.3 Open System configuration



Result logic must be configured so that results can be sent to the LIS. Assay and target(s) name(s) are chosen by the user. For download code, the **test name** chosen by the used will be used.

H|\^&||||||||||||**20140527171834**

P|1||**PatId123**

O|1|**AB99990008**||^^^BDMAX_AND||||||||||**Diagenode EVP**

L|1|N

5.5

5.5.1 Request Fields

The ASTM 1394 protocol defines this as a Request Information Record message. A download Request record is also known as a "Query". The only type of download "Query" request that the BD MAX instrument accepts is a request for test results. A Terminator record with a termination code of "F"(processed) or "Q"(error) is used to signal the last packet of a query response. If a query request was invalid, the instrument interface responds with only the Terminator record with a termination code of "Q". If the instrument interface cannot locate any specimens in the active or history databases that meet the query criteria, it responds with only the Terminator record with a termination code of "F".

A query contains a set of request parameters that are used to determine which specimen(s) to access. The following tables define the ASTM 1394 Request record fields that can be transmitted from the LIS in a Download message and are accepted and acted upon by the BD MAX.

The Starting Date/Time to Ending Date/Time range is important for this query because all tests within the Starting Date/Time to Ending Date/Time will be sent to the LIS when requested, whether or not they have been previously sent.

Request Record Field Name	ASTM Pos.	Direction
Patient ID request field	Q, 3, 1, 1	D
Accession request field	Q, 3, 1, 2	D
Request Test Status	Q, 5, 1, 2	D
Starting Date/Time	Q, 7, 1, 1	D
Ending Date/Time	Q, 8, 1, 1	D
Request Information Status Code	Q, 13, 1, 1	D

Patient ID (Q, 3, 1, 1) – The only accepted value in this field is ALL.

Accession Number (Q, 3, 1, 2) –The only accepted value in this field is ALL.

Test ID (O, 5, 1, 4) – The unique string that identifies the BD instrument type and test type. In the case of the BD MAX instrument, this will always be BDMAX_AND.

Test Status (Q, 5, 1, 2) The BD MAX instrument accepts queries for vials with a status as follows:

INST_POSITIVE = POSITIVE

INST_NEGATIVE = NEGATIVE

CONFIRMED_POSITIVE = CONFIRMED POSITIVES

ALL = POSTIVE & NEGATIVE & CONFIRMED POSITIVES

Starting Date\Time (Q, 7, 1, 1) – Requested starting time for query - the beginning of the Date/Time range for which data should be collected. If it is null the BD MAX will use todays date minus 30 days. Note: the time that is used for any starting date/time is 12:00:00 a.m.

End Date\Time (Q, 8, 1, 1) – Requested Ending time for the query - the ending of the Date/Time range for which data should be collected. It must be greater than the Starting Date/Time or the query will be rejected. If it is null, the BD MAX will use the current date time. Note: the time that is used for any ending date/time is 12:00:00 a.m.

Request Information Status Code (Q, 13, 1, 1) – The following codes are the only codes that will be used in the BD MAX:

A – abort/cancel last request.

P – preliminary results.

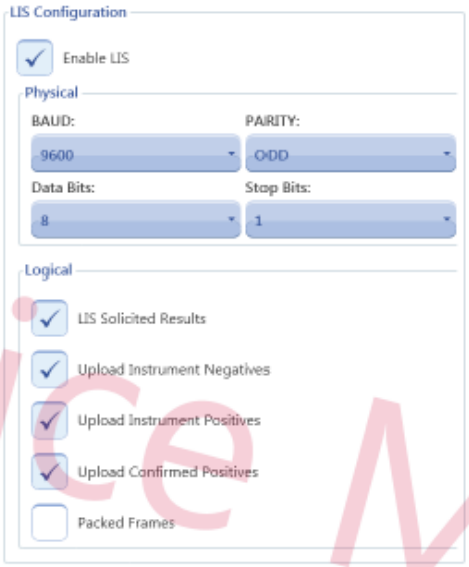
Q|1|ALL^ALL||^CONFIRMED_POSITIVE||20111105120000|20111106223000||||P

6. Configurable Options

There are several aspects of the BD MAX LIS interface that are configurable by the user. The configurable parts of the interface are described below.

6.1 BD MAX LIS Configuration Screen

The BD MAX LIS Configuration Screen allows the user to specify the configurable behavior of the LIS interface. To navigate to the BD MAX LIS Configuration Screen select the Configuration Tab then the External Devices Tab – when logged in as ADMIN, the LIS Configuration Group will be displayed.



The BD MAX LIS interface is configured by enabling and defining fields within the LIS Configuration at the BD MAX computer. There is no standard configuration for a LIS-connection. It depends all how the LIS driver is written and works . If parameters are changed for the LIS configuration and Saved, the new configuration takes effect immediately.

6.2 Enable LIS box

The options for this group are mutually exclusive.

Possible parameters:

ENABLED

DISABLED

Default: DISABLED

6.3 Parameters Group: Physical

Parameters defined in this group control the communication parameters assigned to the USB to a serial communications port that is connected to the LIS. **The following setting have to be selected based on the LIS vendor parameters.**

BAUD

The BAUD parameter allows the adjustment of the speed of the communications link between the LIS system and the BD MAX.

Possible parameters:

1200

2400

4800

9600

19200

Default: 9600

PARITY

The PARITY parameter allows for the adjustment of the error check that can be performed on every character that is received and transmitted.

Possible parameters:

NONE

ODD

EVEN

Default: ODD but most LIS vendor used NONE

DataBits

The Databits parameter allows for the adjustment of the size of the character that is transmitted and received by the Physical Protocol Layer.

Possible parameters:

7 DataBits

8 DataBits

Default: 8 DataBits

STOPBits

The STOPS parameter allows for the adjustment of the number of stop bits that are appended to the characters that are transmitted by the Physical Protocol Layer.

Possible parameters

1 StopBit

2 StopBits

Default: 1 StopBit

6.4 LIS Options Group : Logical

This group allows the user to define the LIS/LAB specific workflow (dictating when data is sent to the LIS) and the types of data that will be sent to the LIS.

LIS Solicited Results

If LIS Solicit Results is enabled (checked) Results will be sent only when the LIS requests results. If this Option is selected **the LIS must actively** ask for new results. The **BDMAX send no** results **active**. This setting depends on the LIS connection parameters.

Default: Solicited

Upload Instrument Negatives

When this checkbox is enabled (checked), Negative results will be uploaded to the LIS, whenever a Results Upload to the LIS occurs. This could occur when the result is called for the test, if so configured, or when a request from the LIS is received for INST_NEGATIVES results and the test has not already been transmitted to the LIS. Need to be discussed with the customer.

Default: Disabled

Upload Instrument Positives

When this checkbox is enabled (checked), *Preliminary final* Positive results will be uploaded to the LIS, whenever a Results Upload to the LIS occurs. This could occur when the result is called for the test, if so configured, or when a request from the LIS is received for INST_POSITIVE results. Need to be discussed with the customer.

Default: Disabled

Upload Confirmed Positives

When this checkbox is enabled (checked), CONFIRMED Positive results will be uploaded to the LIS, whenever a Results Upload to the LIS occurs. This could occur when the user selects the “Save Confirmed Positives” button on the Results, Run Details, PCR Analysis screen, if so configured, or when a request from the LIS is received for CONFIRMED_POSITIVE results. Need to be discussed with the customer.

Default: Disabled

When one run is opened that has results, the user can select “Positives” from the “Group By” combo box. Only the positions with Positive results will be displayed, and each graph will gain a checkbox which will allow the user to confirm the Positive results on that position. Once the user has done that, they will need to click the “Confirm Positives” button at the bottom right of the screen.

Packed frames

If selected BD MAX will send blocks (and also expect blocks).

If un selected (unpacked) BD MAX will send frame by frame and after each line BD MAX will expect an ACK from the listener. This setting depends on the LIS connection parameters.

Annexes

1. List of test/assay and target names:

Test/Assay Name (D) O, 16, 1, 1	Target Name (U) R, 14, 1, 8
BD MAX Cdiff	CDIFF
BD MAX CRE RUO	KPC OXA-48 NDM
BD MAX GBS	GBS
BD MAX GC rt PCR	GC
BD MAX MRSA	MRSA
BD MAX StaphSR	SA MRSA
BD MAX MRSA XT	MRSA
BD MAX Ent Bac	Shig STX Campy Salm
BD MAX Ent Parasite	Glamb Ehist Crypto
BD MAX CT GC TV	CT GC TV
BD MAX CT GC	CT GC
BD MAX Vaginal 46	BV Cgroup Ckru Cgla TV

2. Guideline for setting up a connection

This guide should be designed to facilitated installation at site in a concise and clear way. Cable and part should be provided by your local FSE.

1. List of assays and UDP that will be connected to LIS

2. RS232 (COM- Port) and Cables (hardware not provided by BD)
    a. **COM- Port to Network (RJ45) Adapter :** Settings from this part are made by LIS provider
    b. **Moxa- Box**: Settings from this part are made by the local IT.
    c. If you don´t have a COM- Port on your Laptop you have to install a USB to COM- Port Adapter
    d. **Null- Modem Cable:** For all direct connections with a COM- Port you have to use a Null- Modem Cable

3. Make the physical connection of the cables

4. Set the LIS configuration according to the LIS provider parameters and customer options

5. Provide an example of the string for each assays that will be upload/download to and from the LIS to the BD MAX

6. Test the connection for upload and download
    a. For upload; results need to be present in the MAX
    b. For Download; SBT need to be scan first, then test can be downloaded to the worklist.