BD Max

LIS Vendor Interface

Team Sign Off	***Signature***	***Date***
Software Project Lead – *Tom Wojeck*		
Software Test Lead – Matt Ebsworth		
Software Engineer – Jerri Mulholland		
Quality Management – Tom Haynie		

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Table of Contents

1. Purpose ____ *4*

1.1. Related Documents ____ **4**

1.2. Storage ____ **4**

2. Definitions ____ *4*

3. BD ASTM Interface ____ *5*

3.1. Overview ____ **5**

4. LIS Communication Overview ____ *5*

4.1. Physical Cable Interface ____ **5**

4.2. Communication Protocols ____ **5**

4.3. Physical Protocols ____ **6**

4.3.1. Unpacked Frames ____ 6

4.4. Logical Protocols ____ **7**

5. Configurable Options ____ *7*

5.1.1. BD Max LIS Configuration Screen ____ 7

5.1.2. BD Max Configurable Options ____ 8

5.1.2.1. LIS ENABLE Group ____ 8

5.1.2.2. Port Parameters Group ____ 8

5.1.2.3. LIS Options Group ____ 9

6. Message Content ____ *9*

6.1. Field List ____ **10**

6.1.1. Field Descriptions ____ 12

6.1.1.1. Header Fields ____ 12

6.1.1.2. Patient Fields ____ 12

6.1.1.3. Order Fields ____ 12

6.1.1.4. Result Fields ____ 12

6.1.1.5. Request Fields ____ 13

7. Confirmed Positives ____ *14*

1. Purpose

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

1.1. Related Documents

1.2. Storage

This is a Microsoft Word 97-2003 document.

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.

Preliminary Positive – This is the positive result that is determined by the instrument. It is a preliminary positive until it is 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.

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

3. BD ASTM Interface

3.1. Overview

The BD Max default will be LIS Interface disabled. The LIS Vendor/BD Field Service Engineer must enter various laboratory specific configuration parameters to enable the LIS interface when required for laboratory operations.

When the BD Max completes a run, if the LIS is enabled and unsolicited mode is configured, the configuration settings for the result upload will be checked. If the user has configured the LIS to upload instrument negative results, the negative final calls will be uploaded to the LIS. If the user has configured the LIS to upload instrument positive results, the instrument positive final calls 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 final call to the LIS. The user will be able to confirm the positive result on the Results, Run Details, PCR Analysis screen. The user will then have the ability to press the Save Confirmed Positives button. This will save the confirmed positive result to the database. 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: the uploading of negative and positive final calls and confirmed positives are not currently available in Open System Testing because results are not called on OSR tests.

The BD Max will accept result request queries from the LIS when the LIS is enabled. The result information that will be sent to the LIS will be 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 positive, instrument negative, 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 Administrator/LIS screen. The default setting for all upload types is disabled. The default setting for Solicited uploads is enabled. This screen will only be accessible to users that have *ADMIN* permission level.

4. LIS Communication Overview

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.

4.1. Physical Cable Interface

The BD Max instrument communicates to the LIS by using an RS232 serial port connected to a USB to RS232 conversion interface. The serial port interface used by the instruments uses only 3 signals in the interface cable, Transmit Data (Pin 2), Receive Data (Pin 3), and Signal Ground (Pin 5). Becton Dickinson does not believe that the inclusion of additional signals will cause any problems for the interface, however Becton Dickinson has not tested this case.

4.2. Communication Protocols

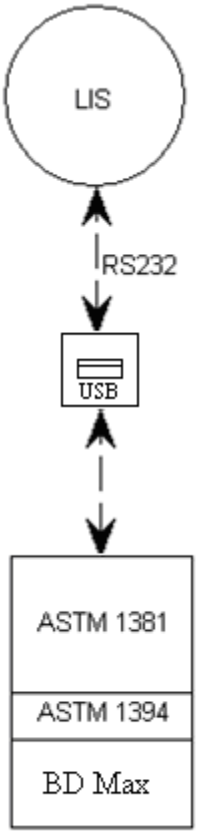
The American Society for Testing and Materials (ASTM) has published standards for how information should be exchanged between a clinical instrument and lab computer system. BD has implemented communication software to adhere to these specifications.

The ASTM committee has produced standards describing both the logical level formatting and the physical exchange of data across a serial port. The logical level formatting describes how to place

individual pieces of medical information into a record string, and how to combine record strings into a properly formatted message string. The physical level protocol describes how logical level message strings can be partitioned and passed across an RS232 line to an LIS.

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. A later section in this document discusses any deviations from that specification.

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.



4.3. Physical Protocols

The BD LIS interface implements the ASTM E_1381 physical level protocol as outlined in the published specification except for the deviations described below.

4.3.1. Unpacked Frames

Becton Dickinson 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 are packed to 240 bytes and the last frame containing that logical record is less than 240 bytes.

The BD LIS interface is configurable to send either packed frames or unpacked frames, which contain a single record per frame. (The BD simulator described in a later section also has this configurable option).

4.4. Logical Protocols

The BD LIS interface implements the ASTM E_1394 logical level protocol as outlined in the published specification except for the deviations described below.

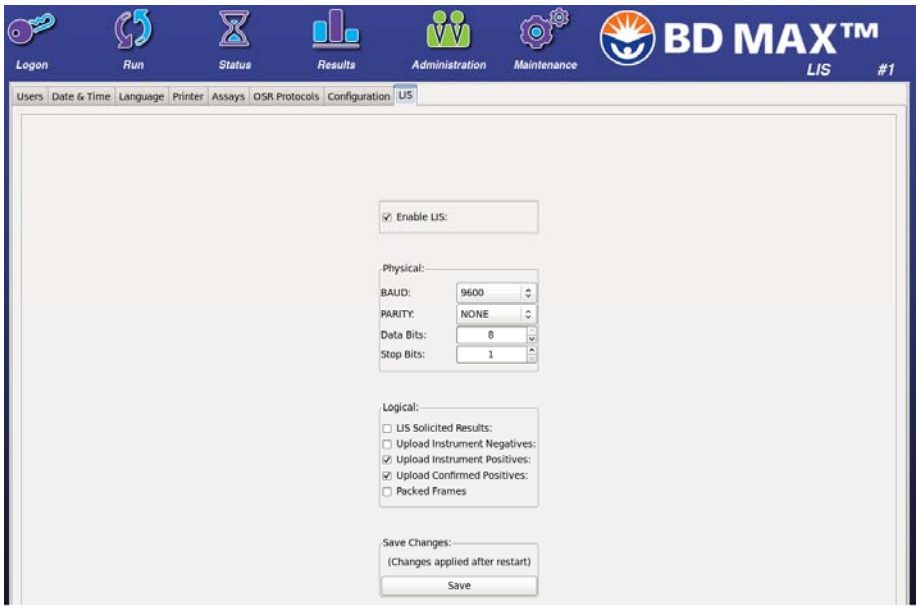
5. Configurable Options

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.

5.1.1. 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 Administration Tab then the LIS Tab – when logged in as ADMIN, the LIS Configuration Group will be displayed.

Screen Prototype:



The BD MAX LIS interface is configured by enabling and defining fields within the LIS Tab at the BD Max instrument. If parameters are changed for the LIS configuration, the new configuration takes affect after the instrument is rebooted.

5.1.2. BD Max Configurable Options

5.1.2.1. LIS ENABLE Group

The options for this group are mutually exclusive.

Possible parameters:

ENABLED

DISABLED

Default: DISABLED

5.1.2.2. Port Parameters Group

Parameters defined in this group control the communication parameters assigned to the USB to a serial communications port that is connected to the LIS

5.1.2.2.1.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

5.1.2.2.2.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: NONE

5.1.2.2.3.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

5.1.2.2.4.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

5.1.2.3. LIS Options Group

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.

5.1.2.3.1.Upload Instrument Positives

When this checkbox is enabled (checked), *Preliminary* 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.

Default: Disabled

5.1.2.3.2.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.

Default: Disabled

5.1.2.3.3.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.

Default: Disabled

5.1.2.3.4.LIS Solicited Results

If LIS Solicit Results is enabled (checked) Results will be sent only when the LIS requests results.

Default: Solicited

6. Message Content

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

6.1. 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). A blank column indicates that the field is not to be exchanged with an LIS. Fields not configured to be exchanged with the LIS are ignored in a download message.

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. 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	H, 5, 1, 1	U
Version Number	H, 13, 1, 1	U
Message Date/Time	H 14, 1, 1	U

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

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

Result Record Field Name	ASTM Pos.	Direction
Result ID Code	R, 3, 1, 4	U
Test Status	R, 4, 1, 1	U
User Result Identifier	R, 4, 1, 2	U
Preliminary/Final Status	R, 9, 1, 1	U
Test Start Date Time	R, 12, 1, 1	U
Instrument Type	R, 14, 1, 1	U
Instrument Number	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

Request Record Field Name	ASTM Pos.	Direction
Patient ID request field	Q, 3, 1, 1	D

Request Record Field Name	ASTM Pos.	Direction
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

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

6.1.1. Field Descriptions

This section provides detailed information for each field listed in the previous section.

6.1.1.1. 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

6.1.1.2. Patient Fields

Patient ID (P, 4, 1, 1) – Identifier that uniquely identifies a patient. This field can be up to 20 characters long.

P|1| |PatId123

6.1.1.3. Order Fields

Accession Number (O, 3, 1, 1) – The unique alphanumeric string that identifies a specimen. This field can be up to 20 characters long. 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.

O|1|23878||^^^BDMAX_AND

6.1.1.4. Result Fields

Once a result has been successfully sent to the LIS in the unsolicited mode of operation, it will not be resent to the LIS. If the BD Max is configured for Solicited mode operation, any time the result is requested by the LIS, it will be sent to the LIS if it is within the specified date/time range of the request.

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) – The status value for a particular test. This field is filled for all test results. For the BD Max instrument tests, the status code is one of the pre-defined values. The possible values are:

- INST_POSITIVE
- INST_NEGATIVE
- CONFIRMED_POSITIVE

User Result Identifier (R, 4, 1, 2) – A user defined result string. This field is optional. Max length is CHUCK fill this in.

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

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 in section 6.6.2 (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) – – This value indicates the position inside of the instrument where the test was performed.

Test Name (R, 14, 1, 8) – This is the Assay name from the BD Max instrument that was run on a the test. The maximum length of the test name is 40 characters.

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

R|1|^^^AND|INST_NEGATIVE|||||P|||20111106215215||BDMAX_AND^^^1^995-B6-B-TOP-5^^^BD MAX MRSA IUOv3

R|1|^^^AND|INST_POSITIVE|||||P|||20111105075215||BDMAX_AND^^^1^982-B12-B-TOP-12^^^BD MAX MRSA IUOv3|^CONFIRMED POSITIVE

6.1.1.5. 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.

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

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

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

7. Confirmed Positives

The following updates will be made to the Results, Run, PCR Analysis screen to facilitate the setting of an instrument positive result to a user confirmed positive result.

A new column will be added to the grid titled, Confirm Positive.

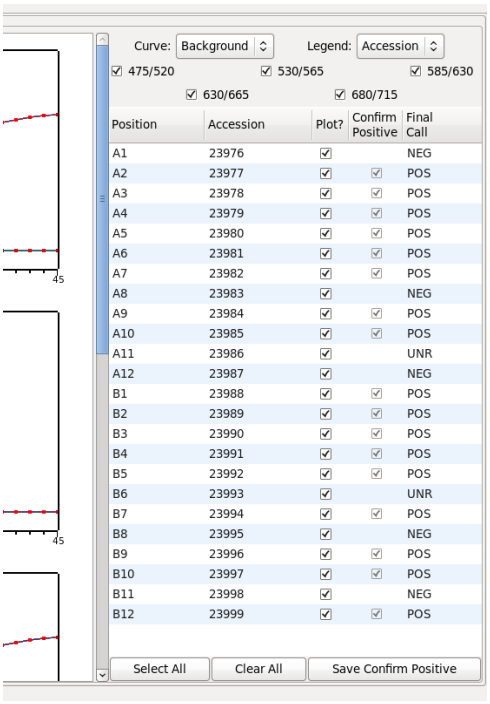
The column will contain check boxes that will be selectable, if the status of the position is instrument positive.

A button will be added at the bottom of the grid section that will give the user the ability to save the confirmed positives.

If the user has unsolicited uploads configured to occur and confirmed positive results to be uploaded, after the “Save Confirmed Positives” button has been pressed, the results will be sent to the LIS as soon as possible.

Once a confirmed positive has been saved, it cannot be “unconfirmed” at the instrument.

Prototype screen:


Curve: Background
Legend: Accession
475/520
530/565
585/630
630/665
680/715
Position
Accession
Plot?
Confirm Positive
Final Call
A1 23976 NEG
A2 23977 POS
A3 23978 POS
A4 23979 POS
A5 23980 POS
A6 23981 POS
A7 23982 POS
A8 23983 NEG
A9 23984 POS
A10 23985 POS
A11 23986 UNR
A12 23987 NEG
B1 23988 POS
B2 23989 POS
B3 23990 POS
B4 23991 POS
B5 23992 POS
B6 23993 UNR
B7 23994 POS
B8 23995 NEG
B9 23996 POS
B10 23997 POS
B11 23998 NEG
B12 23999 POS
Select All
Clear All
Save Confirm Positive