Appendix VI: Data Transfer Protocol

1. Object

This document describes how the Biolyte 2000 transmits data to an external computer.

2. Low-level Protocol (Transfer Link)

This protocol used by Biolyte 2000 is designed according to ASTM E1381-91. There are three distinct phases in transferring information between the instrument and a computer system. The three phases are establishment, transfer, and termination

Note: Biolyte 2000 is always the sender; it cannot be the receiver.

2.1 Establishment phase

- Biolyte 2000 transmits the <ENQ> transmission control character to the intended receiver.
- The receiver has 15 seconds to reply with an <ACK> (if ready) or <NAK> (if not ready) after receiving an <ENQ> character.
- If the receiver responds with an <ACK> character, Biolyte 2000 will proceed to transfer phase.
- If the receiver responds with an <NAK> or any other character (except <ACK>), Biolyte 2000 will proceed to Termination phase.
- If the receiver does not respond within 15 seconds period, Biolyte 2000 will send another <ENQ> character.
- If the receiver does not respond within 15 seconds period again, Biolyte 2000 will proceed to Termination phase.

2.2 Transfer phase

- Biolyte 2000 has 30 seconds to transmit the first frame. If no frame or <EOT> is received within 30 seconds, the receiver will proceed to the Termination phase.
- The receiver has 15 seconds to respond with an acknowledgment control character (<ACK> or <NAK>).
- If the receiver responds with an <ACK> character, Biolyte 2000 will transmit next frame within 30 seconds.
- If the receiver responds with an <NAK> character, Biolyte 2000 will transmit the same frame again within 30 seconds period. If Biolyte 2000 has transmit the same frame 6 times, it will proceed to Termination

phase.

- After all frames have been send, Biolyte 2000 will proceed to Termination phase.

2.3 Termination phase

- Biolyte 2000 transmits an <EOT> character and then regards the data link to be in a neutral state. Upon receiving <EOT>, the receiver also regards the data link to be in the neutral state.

For more details in time and data link between two systems please refer to ASTM E1381-91.

3. High-level Protocol (Transfer Information)

This protocol used by Biolyte 2000 is designed according to ASTM E1394-91. This protocol is intended to apply to the structure of messages exchanged between clinical instruments and computer systems.

The structure of records is described in Table I. The column "ASTM REF" lists the sections of the ASTM E1394-91. The column " ASTM NAME" lists the field names that is defined in ASTM E1394-91. The column "IMPLEMENTATION" lists the data formats of the field.

The frame structure is illustrated as follows:

<STX> FN test <ETX> C1 C2 <CR> <LF>

where:	<STX>	- Start of Text transmission control character
	FN	- single digit Frame Number 0 to 7
	text	- Data Content of Message
	<ETX>	- End of Text transmission control character
	C1	- most significant character of checksum 0 to 9 and A to F
	C2	- least significant character of checksum 0 to 9 and A to F
	<CR>	- Carriage Return ASCII character
	<LF>	- Line Feed ASCII character

Checksum: The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number and the last character is <EXT> character.

4. Reference

4.1 ASTM E1381-91 "Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems"

4.2 ASTM E1394-91 "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems"

Header Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
7.1.1	Record Type ID	Single character: “H”
7.1.2	Delimiter Definition	Standard delimiters: |\^&
7.1.3	Message Control ID	Not used
7.1.4	Access Password	Not used
7.1.5	Sender Name or ID	BioCare^Biolyte^mm..mm^dd..dd “mm..mm” – version of software “dd..dd” – analyzer serial No.
7.1.6	Sender Street Address	Not used
7.1.7	Reserved Field	Not used
7.1.8	Sender Telephone Number	Not used
7.1.9	Characteristics of Sender	Not used
7.1.10	Receiver ID	Not used
7.1.11	Comment or Special Instruction	Not used
7.1.12	Processing ID	Not used
7.1.13	Version No.	This value identifies the version level of the ASTM specification. Single character : “1”
7.1.14	Data and Time of Message	Date and time at which message was transmitted. (This is not the time of the analysis.)

Patient Information Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
8.1.1	Record Type ID	Single character: “P”
8.1.2	Sequence Number	Single character: “1” (This will always be “1” because there will be only one patient record per message.)
8.1.3	Practice assigned patient ID	Not used
8.1.4	Laboratory Assigned Patient ID	Patient ID if a available; otherwise, blank.
8.1.5	Patient ID No. 3	Not used
8.1.6	Patient Name	Not used
8.1.7	Mother’s Maiden Name	Not used
8.1.8	Birthday	Not used
8.1.9	Patient Sex	Not used
8.1.10	Patient Race-Ethnic	Not used
8.1.11	Patient Address	Not used
8.1.12	Reserved Field	Not used
8.1.13	Patient Telephone Number	Not used
8.1.14	Attending Physician ID	Not used
8.1.15	Special Field 1	Not used
8.1.16	Special Field 2	Not used

8.1.17	Patient Height	Not used
8.1.18	Patient Weight	Not used
8.1.19	Patient's Known or Suspected Diagnosis	Not used
8.1.20	Patient Active Medications	Not used
8.1.21	Patient's Diet	Not used
8.1.22	Practice Field No. 1	Not used
8.1.23	Practice Field No. 2	Not used
8.1.24	Admission and Discharge Dates	Not used
8.1.25	Admission Status	Not used
8.1.26	Location	Not used
8.1.27	Nature of Alternative Diagnostic Code and Classifiers	Not used
8.1.28	Alternative Diagnostic Code and Classification	Not used
8.1.29	Patient Religion	Not used
8.1.30	Marital Status	Not used
8.1.31	Isolation Status	Not used
8.1.32	Language	Not used
8.1.33	Hospital Service	Not used
8.1.34	Hospital Institution	Not used
8.1.35	Dosage Category	Not used

Test Order Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
9.4.1	Record Type ID	Single character: "O"
9.4.2	Sequence Number	Single character: "1" (This will always be "1" because there will be only one order per message.)
9.4.3	Specimen ID	Not used
9.4.4	Instrument Specimen ID	Sample serial No.
9.4.5	Universal Test ID	Not used
9.4.6	Priority	Not used
9.4.7	Requested/Ordered Date and Time	Not used
9.4.8	Specimen Collection Date and Time	Not used
9.4.9	Collection End Time	Not used
9.4.10	Collection Volume	Not used
9.4.11	Collection ID	Not used
9.4.12	Action Code	Not used
9.4.13	Danger Code	Not used
9.4.14	Relevant Clinical Information	Not used
9.4.15	Date /Time Specimen	Not used

	Received	
9.4.16	Specimen Descriptor	“Serum/Plasma”, “Whole Blood”, Urine”
9.4.17	Ordering Physician	Not used
9.4.18	Physician’s telephone Number	Not used
9.4.19	User Field No. 1	Not used
9.4.20	User Field No. 2	Not used
9.4.21	Laboratory Field No. 1	Not used
9.4.22	Laboratory Field No. 2	Not used
9.4.23	Date/Time Results Reported or Last Modified	Not used
9.4.24	Instrument Charge to Computer System	Not used
9.4.25	Instrument Section ID	Not used
9.4.26	Report Types	“P” – preliminary results(Results require remote review)
9.4.27	Reserved Field	Not used
9.4.28	Location or Ward of Specimen Collection	Not used
9.4.29	Nosocomial Infection Flag	Not used
9.4.30	Specimen Service	Not used
9.4.31	Specimen Institution	Not used

Result Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
10.1.1	Record Type ID	Single character: “R”
10.1.2	Sequence Number	Counts the items sent for this order; ‘1’ for the first items, ‘2’ for the second, etc.
10.1.3	Universal Test ID	Five parts The first three parts are not used (see sections 6.6.1.1-6.6.1.3 of ASTM E1394-91). The fourth part is item name assigned by BioCare. Which are defined below: “Cl-” - chloride concentration “Na+” - sodium concentration “K+” - potassium concentration “Li+” - lithium concentration The fourth part is item type; it will be one of the following: M – measured C - Calculated
10.1.4	Data or Measurement Value	Value of the parameter as an ASCII string. “±###.##” – if too many digits
10.1.5	Units	Concentration unit “mmol/L” “mEq/L”

10.1.6	Reference Ranges	Not used
10.1.7	Result Abnormal Flags	Not used
10.1.8	Nature of Abnormality Testing	Not used
10.1.9	Result Status	Not used
10.1.10	Date of Change of Instrument Normative Values or Units	Not used
10.1.11	Operator Identification	Not used
10.1.12	Date/Time Test Started	Date and time at which the analysis started. (This field will be used only in the first result record.)
10.1.13	Date/Time Test Completed	Not used
10.1.14	Instrument Identification	Not used

Message Terminator Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
13.1.1	Record Type ID	Single character: “L”
13.1.2	Sequence Number	For this record type this is always “1”.
13.1.3	Termination Code	“N” - normal termination “T” - sender aborted

Example

This example includes both low-level and high-level protocol.

The responses from computer are shown as <ACK>.

Example data:

- Instrument: Biolyte
- Software version: 2.1.1.1
- Analyzer serial No.: 5
- Patient ID: 123456789
- Sample type: Serum/Plasma
- Sample serial No.: 12
- Date and time analyzed: Oct 29, 1999 08:50:59
- Date and time transmitted: Oct 29, 1999 10:36:31
- Item result:

  Na+ : 167 mmol/L

  K+ : 7.2 mmol/L

  Cl- : 151 mmol/L

Transmit format:

<ENQ>

<ACK>

<STX>1H|\^&|||BioCare^Biolyte^1.2.1.1^5|||||||1|19991029103631<CR><ETX>c3
<CR><LF>
<ACK>
<STX>2P|1||123456789 <CR><ETX>34<CR><LF>
<ACK>
<STX>3O|1||12||||||||||Serum/Plasma|||||||||P<CR><ETX>2b<CR><LF>
<ACK>
<STX>4R|1|^^^Na+^M| 167
|mmol/L|||||||19991029085059<CR><ETX>ea<CR><LF>
<ACK>
<STX>5R|2|^^^K+^M| 7.2 |mmol/L<CR><ETX>30<CR><LF>
<ACK>
<STX>6R|3|^^^Cl-^M| 151 |mmol/L<CR><ETX>21<CR><LF>
<ACK>
<STX>7L|1|N<CR><ETX>09<CR><LF>
<ACK>
<EOT>