RIC CO. L.T.D. CONFIDENTIAL Clinical Chemistry Analyzer CA-270 Host Interface

FURUNO ELECTRIC CO., LTD., 2016/07



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REVISION RECORD

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			REVISION RECORD	
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Chapter 1 Introduction

This document specifies the communication scheme between the CA-270 Clinical Chemistry Analyzer (hereinafter called Analyzer) and the Host Computer (hereinafter called Host). The construction of this on-line system enables communication between the Analyzer and the Host, and retrieval of the measurement results from the Analyzer in response to an external order.

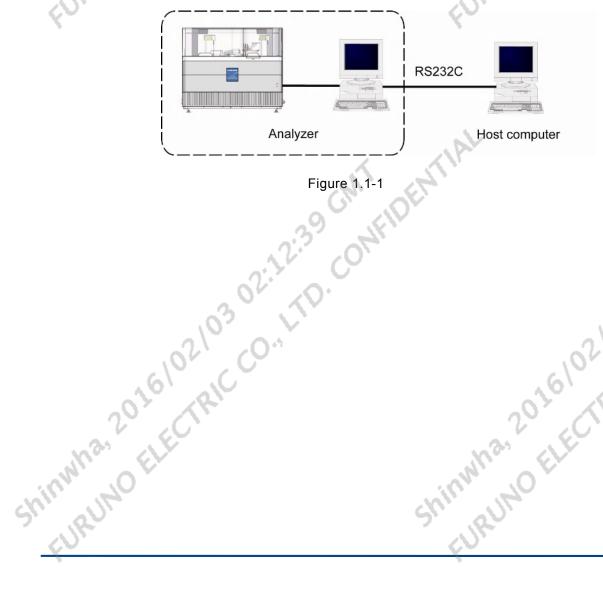
For more understanding the operation of the Analyzer, refer to the Operator's manual (or Service manual).

This on-line system defines each item as a protocol within the conformity of the following standards:

Low level control : ASTM E1381-95 High level control : ASTM E1394-91

System configuration

The communication between the Analyzer and the external Host is conducted with the RS232C interface. The interconnection between them is shown below:



Chapter 2 Low level control

2.1 **Physical Layer**

2.1.1 **Communication specifications**

	•	h as connectors, cables, and protocol which s between Host and Analyzer, are given in th	-
1	Physical Layer	01. 0.	07.
2.1.	1 Communicatio	n specifications	103 17
	Item	Specifications	Default value
1	Transmission mode	Synchronous RS232C start-stop transmission Half-duplex	26/0 210
2	Transmission rate	300 / 1200 / 2400 / 4800 / 9600 / 19200	9600bps
3	Transmission code	ASCII	31
4	Date length	7 bits / 8 bits	8 bits
5	Parity	Odd / even / none	Even parity
6	Stop bit	1 bit / 2 bits	1 bit

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Connectors

Connector on the Analyzer is a D-sub 9pin Male. Connector at the Analyzer side of cable is a D-sub 9pin Female.

Pin assignment 2.1.3

Connector at	the Analyzer	side of cable	is a D-sub 9pin Female.
2.1.3 Pin ass	ignment		~
	Pin number	Signal	CMT DENTIAL
		designation	M' CH'
	1	CD	C. 100
	2	RD	O CM, I DEM,
	3	TD	(0)
	4	DTR	· ·
	5	GND	
	6	DSR	
	7	RTS	
A	8	CTS	
20	9	RI	
20	. (0		
My			γ_{μ}
100			
Sh. On			Shiral
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Interface signals 2.1.4

Table 1 Functions of interface signals

Abbreviation	Signal designation	Function
CD	Carrier Detect	Not monitored.
RD	Receive Data	Pin for data reception
TD	Transmit Data	Pin for data transmission
DTR	Data Terminal Ready	Set to ON when host communication is ready
GND	Signal Ground	Ground
DSR	Data Set Ready	Monitor the host. When this is OFF, host may be turned off or
~0 ×	XIV.	cable is broken.
RTS	Request To Send	Set to ON while data reception is available. Set to OFF when
y. (1)		the data buffer is full and cannot receive data.
CTS	Clear To Send	Wait data transmission till this becomes ON.
RI	Ring Indicator	Not monitored.

Cable specifications

The cable for host communication is RS-232C with the following cable connection.

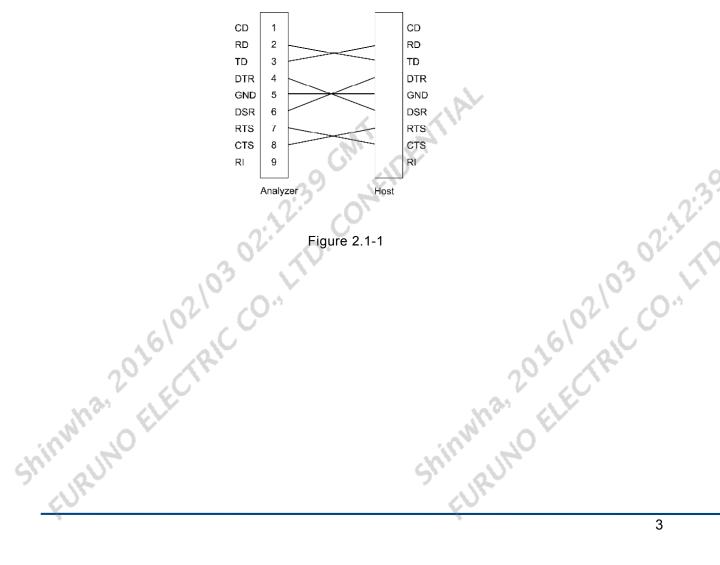


Figure 2.1-1

2.2 **Data Link Layer**

2.2.1 Summary of transmission control characters

Analyzer	is shown in the following s	sub clauses.	nge of messages between Host and	3
	mary of transmissio		200	,,,
Designation	Meanings	ASCII code	Remarks	1
ENQ	Acknowledge	05H	Request for transmission	
EOT	End of Transmission	04H	Link opening	
ACK	Acknowledge	06H	Positive acknowledgement	
NAK	Negative Acknowledge	15H	Negative acknowledgement	
STX	Start of Text	02H	Start of text	
ETX	End of Text	03H	End of text in the final frame	
ETB	End of Transmission Block	17H	End of text in the intermediate frame	

Message composition

SD,	1	2							SV	n-1 n
Field #	1)	2)	3)	4)	5)	6)	7)	8)	9)	
Item	S T X	F N	TEXT	C R	E T X	C 1	C 2	C R	L F	(n≤ 247)

Field #	Item	Data length	Description	
1)	STX	1	To indicate the start of frame (ASCII code: 02H)	
2)	FN	1	Sequence number of frame (0 – 7) (Note 1)	
3)	TEXT	239	Text (Note 2)	
4)	CR	1	(ASCII code: 0DH) (Note 2)	
5)	ETX	1	To indicate the end of frame (ASCII code: 03H) (Note 3)	200
6)	C1	1	The upper digit of checksum (Note 4)	2:
7)	C2	1	The lower digit of checksum (Note 4)	2:3
8)	CR	100	(ASCII code: 0DH)	20, 40
9)	LF	(0)	(ASCII code: 0AH)	10,5 r,
	2, 3, 4,	5, 6, and 7)	number assigned to each frame and the ASCII text (0, 1 is cyclically used. At reception of message with same handle as duplicate of re-transmission and discard the	BIC CO.,

Note:

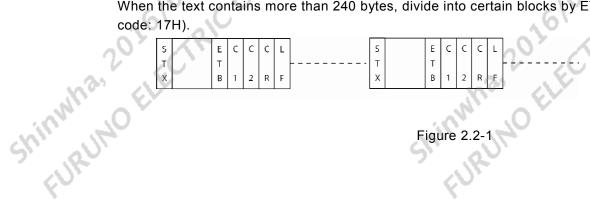
- 1. FN is the sequence number assigned to each frame and the ASCII text (0, 1, 2, 3, 4, 5, 6, and 7) is cyclically used. At reception of message with same sequence number, handle as duplicate of re-transmission and discard the message. Messages divided with ETB will have new sequence number. Initial value shall be "1".
- TEXT is the division of ASCII text message itself and the number of characters for one text is limited to less than 240 characters (including "CR") and below.

(Addition of "CR" is optional settings. Tick on "Send with CR" by clicking

the [Details] button at the Host communications area in the "System Setup 1" Add "Send with CR" when conforming ASTM rules.) screen.)

- 3. ETX code (ASCII code: 03H) or ETB code (ASCII code: 17H)
- 4. In the checksum (Hex) frame, calculate the sum of bits of each message from FN to ETX excluding STX and use last two digits. In the checksum calculation, apply shift JIS code for Kanji code (2-byte characters) and add after breakdown into 1 high byte + 1 low byte. When the checksum does not match, discard the message.

When the text contains more than 240 bytes, divide into certain blocks by ETB (ASCII code: 17H).



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Figure 2.2-1

2.2.3 Transmission procedure

Transmission of data from Analyzer to Host

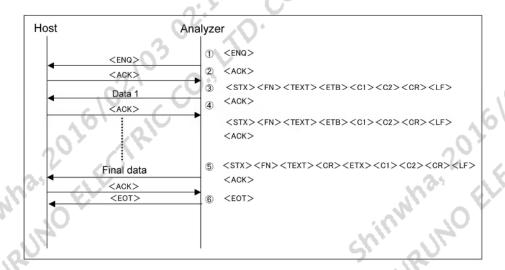


Figure 2.2-2

The control codes are shown in < > in the following figure.

- 1. Analyzer transmits <ENQ> in order to establish a data link.
- 2. <ACK> is sent from Host after it is ready for communication.
- 3. Data 1 (intermediate frame) <ETB>
- ਰ> e data cor e) <ETX> Shinwha, 2016 102 103 02:12:35 CO.LTD When Host has received the data correctly, <ACK> is sent to the analyzer.

2.2.4 Host interface specifications Status transition table

Status transi	tion table	27	-		-							
	Sending data exist	No sending data	ENQ reception	ETX, ETB reception	EOT reception	ACK reception	NAK reception	Data reception	Connection established timeout T1 (15sec.)	Data transmission timeout T2 (15sec.)	Data reception timeout T3 (30sec.)	Data reception interruption timeout T4 (15sec.)
Initialization	Send ENQ.Start T1 timer.Status to"Establishing connection"	No action	Send ACK.Start T3 timer.Status to "Data reception"	No action	No action	No action	No action	No action	No action	No action	No action	No action
Establishing connection	No action	No action	Stop T1 timer.Wait 1 sec.Send ENQ.Start T1 timer.	No action	No action	 Stop T1 timer. Send data. Start T2 timer. Status to "Waiting response." 	Send ENQ. Restart T1 timer.	No action	Stop T1 timerSend EOT.Status to"Initialization."	No action	No action	No action
Connected	 Send data. Start T2 timer. Status to "waiting response". 	Send EOT.Status to"Initialization."	No action	No action	No action	No action	No action	No action	No action	No action	No action	No action
Waiting response	No action	No action	No action	No action	 Stop T2 timer. Send EOT. Start T4 timer. Status to "Initialization 2." 	Stop T2 timer.Status to"Establishing connection."	● Resend data. • Restart T2 timer	No action	No action	 Stop T2 timer. Send EOT. Return data. Status to "Initialization." 	No action	No action
Data reception	No action	No action	No action	Restart T3 timer Status to "Completing data reception"	• Stop T3 timer. • Status to "Initialization."	No action	No action	Restart T3 timer Data reception. Send ACK/NAK.	No action	No action	 Stop T3 timer. Discard corrupted received data. Status to "Initialization." 	No action
Completing data reception	No action	No action	No action	No action	Stop T3 timer.Status to"Initialization."	No action	No action	No action	No action	No action	 Stop T3 timer. Discard corrupted received data. Status to "Initialization." 	No action
Initialization-2	No action	No action	Stop T4 timerSend ACK.Start T3 timer.Status to "Data reception"	No action	No action	No action	No action	No action	No action	No action	No action	Stop T4 timer.Status to"Initialization."

Note:

- Wait timer between characters is 100ms. At time out, the action will be the same as receiving NAK.
- At data re-transmission, sequence number should be the same as original data transmission.
- At data reception, characters before STX and after ETB and ETX should be discarded.
- All received data without sequential sequence number should be discarded.
- Maximum retry of data re-transmission is five times. After the fifth retry, EOT will be sent and change status to initialization. Error must be displayed in this condition.
- Host should return status to initialization after no connection for 20 seconds from the analyzer.
- Maximum retry for ENQ is ten. After the tenth retry, generate an error then start over.

High level control **Chapter 3**

3.1 **Command Record**

ol		le indicates usage of the co	ommand re	cord types.	T	
	Type	Function name	Level	Transmission	Reception	20.
1	Н	Message Header Record	0	Used	Used	0.
2	Р	Patient Information Record	1	Used	Used	
3	0	Test Order Record	2	Used	Used	00
4	R	Results Record	3	Used	Used	C
5	С	Comment Record	-	Used	Used	
6	Q	Request Information	-	Used	Not used	7
U		Record		00		
7	CL	Message Terminator	0	Used	Used	
- 2		Record		Way.		
8	S	Scientific Record	1	Not used	Not used	
9	М	Manufacturer Information	-	Not used	Not used	
		Record	200	, ///		

Level: 0 (Higher) > 3 (Lower)

Data Character Code

Co	ode (Decimal system)	
0-3	1	7, 9, 11, 12, 13 can be used.
13		Reserved as record terminator.
32-	126, 128-254	Allowed.
127	7,255	Not allowed.
No	te: When double quota	ation (ASCII34) is found, discard it (do not treat as data.)
Shinwha. 20	1610210302:3 ELECTRIC CO.	2:39 CONFIDENT. Shirwha, 2016 102 103 Shirwha, 2016 10 ELECTRIC
Shinnina. 20	te: When double quota	2:39 CMFIDENTS

Common fields 3.3

3.3.1 Sequence number

3.4

	Every transmissi	ion incre	ement the nu	umber by "1'	". The num	e. Initial value shall be " ber will set back to "1" a mand with higher level.	
	(Refer to notes b				710.0.	101100 11101 111 <u>0</u> 1121 12	2
ļ	H: Message	heade	er record	V			10,
r		de	70		L. 1	io.	V 10"
						ch messages are	
	exchanged. In and escape delin		specilles ead	sh delimiter	character 101	or field, repeat, componer	nt,
Field	77	Max.	Process	This	Omission	Process on	1
#	Designation.	digits	upon	system	Omission	transmission from	1
	Was Ch	0.9	reception	used/unus		Analyzer	
1	W. O.	'	from Host	ed			
1)	Record type	1	Abandoned	used	Disapproved	Record type "H"	
2)	1 1 1 1 1	4	Abandoned	used	Disapproved	Delimiters established in	
		'	!	1		this system (, back	
	(T	'		l'		slash, ^ and &)	
3)	Message	0	-	unused	-	-	
	control ID	<u> </u>					
4)	Access	0	- '	unused	-	-	
<u> </u>	password	<u> </u>	<u> </u>	<u> </u>	<u> </u>		
5)	Name of	32	Abandoned	Used	Disapproved	Name of Analyzer	
	Analyzer	<u> </u> '	<u> </u>	<u> </u>		defined in this system.	
6)	Address of	0	-	Unused	J /	11	
<u> </u>	sender	<u> </u> '	<u> </u>	L 5	1		
7)		0	-	Unused	- ~	<u> </u> -	
8)	· ·	0	-	Unused	-21/2	-	
	number of	'		1.3	711.		- 1
	sender	<u> </u> '		L. C			2
9)		0	- 0', Y	Unused	-	-	0.7
<u> </u>	of sender	<u> </u> '	OV	-0.	<u> </u>		0"
10)	· ·	0	3	unused	-	-	1810 CO. L
11)	·	0	0.	Unused	-	-	-10. V
	instruction	121	-/On	<u> </u>	<u> </u>		いっつ。
12)		0	- 0	Unused	-	- (1)	, 0
13)	-	0	U	unused	1	10,	10
14)) Date and Time	14	Abandoned	used	Disapproved	Date and time at	V.
	V	10°	!			transmission:	
	0.1		'	1 '		YYYYMMDDHHMMSS	

Meaning of "used/unused": Used: Data available at transmit side

Unused: No data at transmit side

Meaning of "Omission": Disapproved: Omission is not approved

> Approved: Omission is approved.

The item is not used in this system and thus must be omitted.

3.5 P: Patient information record

The string is sent from the Host to the Analyzer at ordering test requests. This is also sent from the Analyzer to the Host when sending test results which as specified by the Host.

Γ	Field	Designation	Max.	Process upon	This	Omission	Process on
	#	Designation	digits	reception from	system	Omission	transmission from
	"	.0	uigits	Host	used/unus		Analyzer
		2	.0	ń	ed		2
	1)	Record type	. 1	Abandoned	used	Disapproved	Record type "P"
	2)	Sequence	6	Abandoned	Used	Disapproved	Refer to "3.3.1".
	C	number					12 Ch
	3)	Patient ID	13	Used for	Used	Disapproved	Send as received.
	20			transmission,		200	
		C.V.		display, and		1/1/	67
Shinnib	0)		print.		All I	0 '
MII.	4)	Laboratory	0	-	Unused	11. 16	¥
2, 0		assigned			2,	100	
SO,		Patient ID				SO,	
*	5)	Patient ID	0	-	Unused	- "	-
-	0)	# 3	00	Handfor	I II	A	0
	6)	Patient Name	36	Used for	Used	Approved	Send as received.
				transmission, display, and			
				print. Up to 18			
				characters.			
	7)	Mother's	0	-	Unused	4 00	-
		Maiden Name					
	8)	Date of birth	8	Used for	Used	Approved	Send as received.
				transmission,	10°	(*1)	
				display, and	76.		
				print.			
-			-01	YYYYMMDD			
	9)	Gender	100	Used for	used	Approved	Send as received.
		_3	5	transmission,		(*2)	3
		10		display, print,			10.
		2	/O	and normal range			0361051CC
		6/0		judgment. M:			
	-	10, 21		Male			10, 210
	00), VL		F: Female U:			0, 14
	- 1	SO.		unknown (*2)			, 50,
30	10)	Race	16	Used for	used	Approved	Send as received.
M,	- 0			transmission,		M.	0
	110	7		display, and	0.4	10. "	2
300	n,			print.	5	. "O),	
	11)	Patient	0	-	Unused	11/2	-
200		Address				60	

		1					,
	12)	Reservation	0	-	Unused	- 65	-
	13)	Phone Number	0	-	Unused	-0V	-
	14)	Attending	32	Used for	Used	Approved	Send as received.
		Physician ID		transmission,	7		
		-		display, and	\O ,		
				print.	U		
	15)	Special Field 1	13	Used for	used	Approved	Send as received.
	.0,	Special Field 1	.5	transmission,	3000		20114 40 10001704.
			2)	display, and			Send as received. Send as received.
-	4.0\		Or	print.			
	16)	Special Field 2	0	Used for	Used	Approved	Send as received.
		~3~	,0	transmission,			23.
		20		display, and			20.
		- V	.0	print. (*3)			7. V
	17)	Patient Height	0	-	Unused	-	- X (2)
-	18)	Patient Weight	0	-	Unused	-	M, C.
	19)	Patient Known	0	-	Unused		70
d	0,	or Suspected				50,	11/2
-		Diagnosis				7	12.
	20)	Patient Active	0	-	Unused	- <	7),
		Medications					
Ī	21)	Patient Diet	0	-	Unused	-	-
	22)	Practice Field	0	-	Unused	-	-
		#1					
Ì	23)	Practice Field	0	-	Unused	-	-
	- /	#2					
ŀ	24)	Admission and	0	_	Unused	- 1	
	,	Discharge	-		_	_/\	
		Dates				.47	
	25)	Admission	0	_	Unused	- 0	_
	23)		U	-	Jiluseu	NO.	_
	26)	Status	70	Hood for	Used	Approximat	Cond on received
	26)	Location	70	Used for	Used	Approved	Send as received.
				transmission,	α		
				display, and	A		
				print.	Y.		
	27)	Nature of	0	(2)	Unused	-	-
		Alternative	~ \\				
		Diagnostic	Or.	69"			. 0
		Code and	1				610
		Classifiers	1				Send as received.
	28)	Alternative	0	_	Unused	-	320, EC
		Diagnostic	C.				100
		Code and					1000
	0	Classifiers					The Ch
Ī	29)	Patient	0	-	Unused		0, 0
_1	V11.	Religion				10/1	12
9	30)	Marital Status	0	-	Unused	. 5	00
	31)	Isolation Status	0	_	Unused		1),
L	0.7	issiation otatus			- Jiladea		

Software Specifications CA-270 Host Interface

32)	Language	0	140.	Unused	-	-
33)	Hospital	0	- C/2	Unused	-	-
	Service		0			
34)	Hospital	0	2.5	Unused	-	-
	Institution	4	CV VO			
35)	Dosage	0		Unused	-	-
	Category	On	₹ O,			. (

Note:

- 1. When "Date of Birth" is omitted, "G2" will be used for normal range.
- 2. When "Gender" is omitted, "Unknown" will be used for "Gender" rale" w When selecting except "F: Female for "Gender", "Male" will be used for normal range.
- 3. Note 3: Code for "Blood type"

	2. WI	nen "Gender" is	s omitted, "l	Jnknown" wil
Shinwha, 2016	WI	nen selecting exce	ot "F: Femal	e for "Gender
1/2	no	rmal range.		
20,	3. No	te 3: Code for	"Blood type"	is as follows:
V	Code	Blood type		
No. V	1	A Rh+		W3
M_{II} , $\sim K$.	2	A Rh-		u_{i} .
10, 70	3	B Rh+		Shinnha
SIL. "IL	4	B Rh-		91, 1
3. 18.	5	O Rh+		3. 18.
SO.	6	O Rh-		CO.
	7	AB Rh+		
	8	AB Rh-		
Shinwha 2016 Shinwha 2016	ECT	03 02:12:39	CONFID	ENTIAL

3.6 O: Test Order Record

Field #	Designation	Max. digits	Process upon reception from Host	This system used/unus ed	Omission	Process on transmission from Analyzer	2:
1)	Record type	1	Abandoned	used	Disapproved	Record type "O"	0.0.
2)	Sequence number	6	Abandoned	Used	Disapproved	Refer to "3.3.1".	100
3)	Sample ID	15	Used for measurement process. Sample ID: 001-99999999 99999999999999999999999999	Used	Disapproved	Process on transmission from Analyzer Record type "O" Refer to "3.3.1". Send as received.	Rico
6.	RUP		91000001-9999 9999)		210.	,RUP	
4)	Equipment specimen ID	0	-	Unused	-	, , , , , , , , , , , , , , , , , , ,	
5)	Universal Test	100	Used for measurement process. (*1)	Used	Disapproved	Send as received.	
6)	Priority	0	-	Unused	-	-	
7)	Date and time of order	0	-	Unused	-	_	
8)	Date and time of sample extraction	14	YYYYMMDDH HMMSS	Used	Disapproved	Send as received or inputted.	
9)	Date and time of completion of sample extraction	0	2.323	Unused		-	-0: ²
10)	Extracted volume	1 02/	Used for measurement process. 0: Normal 1: High 2: Low others: Normal	Used	Disapproved	Send as received.	10302:1
11)	Name who extracted sample	0	-	Unused	-	Ma, ELEC	
12)	Treatment code	0	-	Unused		, O , E	
13)	Danger code	0	-	Unused		- 112	
14)	Relevant clinical	0	-	Unused	- 2,	IRU	

15)	information Date and time	Ī					
15)	L Date and time	0	- 191	Hayasa			
		0	. 00.	Unused	-	-	
	of receipt of		0.7	16.4.			
	sample		2:1				. 1
16)	Sample type	20	Used for	Used	Approved	Send as received.	
		2	measurement				2.
		0.	process. (*2)			0.	2:32
17)	Sample type	20	Used for	Used	Approved	Send as received.	
	0/0		measurement				00
	. al	10	process. (*2)			. OV (\mathcal{G}^{-}
18)	Specimen	0	-	Unused	-	- 6\	
	Source					10.	
19)	Ordering	0	-	Unused	- /	0, 44	
1	Physician					1 70,	
20)	Physician's	0	-	Unused	- 1000	- /\\	
1/1/2	Telephone				" MIL.		
100	Number				1000	0	
20) 21) 22) 23)	Users Field # 1	0	-	Unused	17	-	
22)	Users Field # 2	0	-	Unused	0	_	
23)	Date/Time	0	_	Unused	-\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	_	
23)	Results			Jiiuseu	Y		
	Reported or						
	Last Modified						
24)		0		Houses			
24)	Instrument	0	-	Unused	-	-	
	Charge to						
	Computer						
	System						
25)	Instrument	0	/	Unused	(-),	-	
	Section ID		Alex-	, (6)	_		
26)	Report Types	0	- C/	Unused	-	-	
27)	Reserved Field	0	- 0	Unused	-	-	
28)	Location or	0	200	Unused	-	-	- 0
	Ward of	d	(b. 10)				20
	Specimen	20	7				7:2
	Collection	Or	20.				1
29)	Nosocomial	0		Unused	-	- 3	
	Infection Flag					-10.	
30)	Specimen	0	- 1	Unused	-	- 200	O_{ij}
	Service	. 0				10.	1
31)	(6.)	0	-	Unused	-	-70, 70	
' '	Institution					0 x 85,	
30)	Collection Nosocomial Infection Flag Specimen Service Specimen	00		Unused	-	3/0.	

Universal Test ID for test order record when ISE of ASTM is separated. (Tick on "ASTM ISE separation" by clicking the [Details] button at the Host communications area in the "System Setup 1" screen.)

Universal	Description
Test ID	9 (21)
(2-digit)	2:3
00	No order
01-60	Clinical chemistry
	Analyzer transmits Universal Test ID with zero
	suppression when the ID # is from "1" to "9".
61	ISE Na
62	ISE K
63	ISE CI
64	Diluted ISE Na
65	Diluted ISE K
66	Diluted ISE CI
81	Serum information (H, L, I)

201610210302:12:35 201610210302:12:35 versal Test ID for test order record when ISE of ASTM is not separated.

S	Universal Test ID (2-digit)	Description	Shinkl
-	61	ISE (Na, K, CI)	× -
	62	Diluted ISE (Na, K, CI)	

Use delimiter "^" for delimiting test ID and use "\u00e4" for multiple entry of test ID.

(Example 1) In case of ordering Test ID #1, O|1|001||<u>^^^01</u>

(Example 2) In case of ordering Test ID #15, 21, and 30, O|1|001||^^^15\pm\^21\pm\^30

The Test ID # is described at each part delimited by "A" when ASTM is not complied.

(Example 1) In case of ordering Test ID #1,

O|1|001||01

(Example 2) In case of ordering Test ID #15, 21, and 30, 0|1|001||15^21^30

Note 2: Sample type is as follows:

Sample type	Description
01	unused
02	Serum
03	Urine
04	Plasma
05	Others

as the "def [Detai' * When "Sample type" is omitted, the selected sample type as the "default Sample Type" is applied at the Sample Type Setting from the [Details] button at the Host communications area in the "System Setup 1" screen.

3.7 R: Result record

The results of the test items are notified.

Γ		he results of the		734			
	Field	Designation	Max.	Process	This	Omission	Process on
	#		digits	upon	system		transmission from
			2.	reception	used/unus		Analyzer
			0,	from Host	ed		
	1)	Record type	1	Abandoned	used	Disapproved	Record type "R"
	2)	Sequence	6	Abandoned	Used	Disapproved	Refer to "3.3.1".
		number	VO.	1			al de
	3)	Universal Test	5	Abandoned	used	Disapproved	Method #: 0 to 3999
		ID .					Refer to the table below.
	4)	Test results	17	Abandoned	used	Disapproved	ZZZZZZZZZZ9.99999
	1	SO.					Decimal point that
3/0	3.5					~3	specified in the
1/10.						n_{II}	[Chemistry Parameter 1]
100	_\C)				100	screen. When the
510,	1/2				6	10, 1	value resulting in the
2, 6						5. 5.	"****", it will be printed
SO.						SD.	as "***".
Shinnin	5)	Unit	8	Abandoned	used	Disapproved	Unit for the test results
	6)	Range of	0	-	Unused	-	-
		reference value					
	7)	Flag	42	Abandoned	used	Disapproved	Followings are sent:
							Technical range code,
							Normal range code,
							Error flag code, Rerun
						XIV"	result flag code, and QC
				. 1	· ·	71.	flag code 1-10. Refer
					, ~(c)		to "3.7.1. Test result
				0	W.		error flag code."
-	8)	When it is within	0	- 33	Unused	-	-
	,	the reference		2:			
		range,	A.	>, C			
-	9)	Status	0	0.	Unused	-	- (
	10)	Date when the	0	-1	Unused	-	- 2
	,	reference value	, -				10,
		is changed.	¿O:	2			2.
-	11)	Operator	0	_	Unused	_	. 10" (
	,	identification			0		.61 .0
-	12)	Date and time of	0	-	Unused	_	- 07
	120	commencement	Ü		Ondoca		25 0.
	21	of test				0	
.00	13)	Date and time of	14	Abandoned	Used	Disapproved	YYYYMMDDHHMMSS
"M.		completion of	ידי	, wandoned	J364	Disappioved	
Shin	16	test					70
211	14)	Instrument	0	_	Unused	7. V	
111	14)		U	-	Jiiuseu		-
		identification					

Universal Test ID for test result record is as follows:

	r test result record is as follows:	1
Universal	Description	
Test ID	29 (61)	a di
(2-digit)	0.3	0.7
00	No order	1
01-60	Analyzer transmits Universal Test ID with zero suppression	2:
	when the ID # has a single digit from "1" to "9".	0, 1
61	ISE Na	3
62	ISE K	
63	ISE CI	1 10 CO.
64	Diluted ISE Na	
65	Diluted ISE K	70. 010
66	Diluted ISE CI	70. VL
81	Serum information (H)	60
82	Serum information (L)	
83	Serum information (I)	
71-80、	Calculated test	O
3011-3040	\$\(\lambda_1\)	
	- IR-	
In case "Full	compliance with ASTM rules",	
Use delimiter	r "^" for delimiting test ID.	
	-	

(Example 1) In case of transmission of the result of the test ID # 61 to the Host,

R|1|^^^61|346|mmol/|||00^01^00||||||20040119143714

In case "Non compliance with ASTM rules",

..ssion
1^00||||||2004 (Example 2) In case of transmission of the result of the test ID # 61 to the Shinwha, 2016 102 103 02:12:36 CO.LTD

 $R|1|\underline{61}|346|mmol/I||00^{0}1^{0}0|||||20040119143714$

Test result error flag code 3.7.1

One result flag by priorities is provided

3.7.1 T €	est resu	It error flag code	, all		
The co	ode of the	result abnormal flags	is provided to	the Host as "Re	esult record".
A. In	case "Fu	II compliance with AS	TM rules",		2:2
	One resu	ılt flag by priorities is p	provided.		2:3
	Code	Description	Priority	Display	20° 20
	Α	Error occurred	1	Error flag	(4)
	2	Technical range over "High"	2	>	2/ 000
,6	<	Technical range below	2	<	Built record.
20,	HH, LL	"Low" Panic range over	3	! 00	V6.
	A	Abnormal range over	4	\$	20
Whas El	Н	Normal range over "High"	5	HWW.	
Shinnha, 201	L	Normal range below "Low"	5	L	
3. 18.	N	Normal	6	No display	
\$10.	LL	Unused.	-	2	
	НН	Unused.	-	-	
	U	Unused.	-	-	
	D	Unused.	-	-	
	В	Unused.	-	1	
	W	Unused.	-	-	

B. In case "Non compliance with ASTM rules",

1. Format of the flag

Shirman File Charles Co. Line Chicago Shirman The format of the flag is 99^99^99^99^99^99^99^99^99^99^99^99 in the order corresponding to Technical range code, Normal range code, Error flag code, Rerun result code, and QC flag code from 1 to 10.

2. Technical range code

Code	Display	Description
00	None	Within Technical range
01	3	Technical range over "High"
02	<	Technical range below "Low"

Normal range code

3.	Normai r	ange code	
10	Code	Display	Description
~0 ×	00	None	Within Normal range
V	01	Н	Normal range over "High"
10° 10° 11	02	L	Normal range below "Low"
"VII. C	03	!	Panic range over
10, 10	04	\$	Abnormal range over
ShirURUM			Shi.
			`

Error flag code

4.	Error flag o	code	DEM
Code	Display	Description	Cause - SPT cannot detect liquid level at ASP. The result of SPT liquid detection at ASP is out of range. SPT cannot detect liquid level at IRU. The result of SPT liquid detection at IRU is out of range.
00	-	Normal	-
01	SS	Sample shortage	SPT cannot detect liquid level at
		0, 0.	ASP.
02	SS	Out of the range of the sample volume	The result of SPT liquid
		10.	detection at ASP is out of range.
03	SI1	Not detected liquid level in sample	SPT cannot detect liquid level at
	- 1	dispensing.	IRU.
04	SI1	Out of detection range in liquid level	The result of SPT liquid
	-0,	when sample dispensing.	detection at IRU is out of range.
05	SI2	Diluted sample shortage	SPT cannot detect liquid level at
2	5 K	,	IRU.
06	SI2	Out of detection range in liquid level of	The result of SPT liquid
110	(O)	diluted sample	detection at IRU is out of range.
07	R1S	R1 reagent shortage	RPT cannot detect liquid level
.0)		when aspirating RI reagent.
08	R1S	Out of detection range in liquid level	The result of RPT liquid
	1110	due to R1 reagent shortage	detection is out of range when
		ado to te re rougem onertago	aspirating RI reagent.
09	R2S	R2 reagent shortage	RPT cannot detect liquid level
00	1120	112 reagent shortage	when aspirating R2 reagent.
10	R2S	Out of detection range in liquid level	The result of RPT liquid
10	1120	due to R2 reagent shortage	detection is out of range when
		due to 112 reagent shortage	aspirating R2 reagent.
11-14	Not used.		dopirating 112 reagent.
15	DS DS	Diluent shortage	RPT cannot detect liquid level
10	ВО	Bluefit Shortage	when aspirating diluent.
16	DS	Out of detection range in liquid level	The result of RPT liquid
10	ВО	due to diluent shortage.	· ·
		due to dilucin dilortage.	aspirating diluent.
17	WS	Wash solution shortage	RPT cannot detect liquid level
17	***	**asir solution shortage	when aspirating wash solution.
18	WS	Out of detection range in liquid level	The result of RPT liquid
10	****	due to wash solution shortage.	detection is out of range when
		due to wash solution shortage.	aspirating wash solution.
19	R1B	Not found R1 reagent bottle.	Not registered the relevant R1
19	VID (Not lound KT reagent bottle.	reagent bottle.
20	R1S	No remaining volume of R1 reagent.	detection is out of range when aspirating diluent. RPT cannot detect liquid level when aspirating wash solution. The result of RPT liquid detection is out of range when aspirating wash solution. Not registered the relevant R1 reagent bottle. The remaining volume of the relevant R1 reagent is 0.
20	KIO	No remaining volume of Ki reagent.	relevant R1 reagent is 0.
21 🗥	R2B	Not found B2 reagent battle	9
21	K2D	Not found R2 reagent bottle.	Not registered the relevant R2
200	Dac	No remaining values of DC server'	reagent bottle.
22	R2S	No remaining volume of R2 reagent.	The remaining volume of the
00.05			relevant R2 reagent is 0.
23-26	Not used.		
27	DB	Not found the diluent bottle.	Not registered the relevant

Code	Display	Description	Cause
		O, 10 _V	diluent bottle.
28	DS	No remaining volume of the diluent bottle.	The remaining volume of the relevant diluent is 0.
29	WB	Not found the wash solution bottle.	Not registered the relevant wash
		2.	solution bottle.
30	WS	No remaining volume of the wash solution bottle.	The remaining volume of the relevant wash solution is 0.
31	EST	Abnormal condition occurs during measurement.	The remaining volume of the relevant diluent is 0. Not registered the relevant wash solution bottle. The remaining volume of the relevant wash solution is 0. Sampling stops due to error.
32	LOT	Mismatched in lot number.	The lot information in the reagent actually loaded is not matched with that registered in the
33	SPW	Failed SPT wash.	[Inventory] screen. Failed the SPT wash. Check the alarm screen for solving the
.,()		4	problem.
34	R1W	Failed RPT wash before R1 dispensing.	Failed the RPT wash before R1 dispensing. Check the alarm
),		· -	screen for solving the problem.
35	R2W	Failed RPT wash before R2	Failed the RPT wash before R2
		dispensing.	dispensing. Check the alarm
		3	screen for solving the problem.
36	Not used.		corden for conving the president
37	Not used.		
38	SPS	SPT is clogged.	SPT step-out from movable area at IRU. Or detects the pipette
			clogged.
40	TE1	The temperature at IRU is too low.	Temperature at IRU < 37-2 (°C)
41	TE2	The temperature at IRU is too high.	Temperature at IRU > 37+2 (°C)
42	TE3	The temperature at RCU is too high.	Temperature at RCU > 15°C
43	Not used.	The temperature at the distance mg	i i i i i i i i i i i i i i i i i i i
50	EXP	Expired the valid term of the reagent.	Used the expired reagent in valid
	270	Expired the valid term, of the reagents	term for measurement.
51	STB	Expired the stability term of the reagent.	Used the expired reagent in stability term for measurement.
52	СТО	Calibration valid term expired.	In case when performing
G	105	Samuation valid term expired.	measurement for the method that not performed calibration
- 1			within the specified term.
53	CXP	Expired the valid term of the QC measurement.	In case when performing measurement for the method
Was El	×		that not performed QC measurement within the
54	SXP	Expired the valid term of the calibrator.	Used the expired calibrator in valid term for measurement.
	IE1	Abnormal response for ISE	No response for measurement

Code	Display	Description	Cause	
		measurement request.	request from ISE unit.	
61	IE2	Not received the measurement result	Cannot receive any result from	
		from ISE unit.	ISE unit.	0210302:1
62	IE	Abnormal condition of ISE unit	Detects abnormal condition of	A.
		2:	the ISE unit.	20:0
70	CA?	Concentration conversion error.	No calibration curves. Or not	0,
		3	performed ISE calibration after	3 1
		10.	power ON.	10.
71	OVR	Concentration conversion error in the	Concentration value: below S1	20°
	. \	calibrator.	or higher than Sn.	0. , 0.
72	LIN	Linearity limit error	Linearity limit error	, ,,
73	PRO	Prozone limit error	Prozone limit error	XX.
74	AB1	Absorbance limit error	Under 2 points within the	C
17.2	ADI V	Absorbance minit error	absorbance limit range.	
75	AB2	Absorbance limit2 error	One point or more beyond and 2	
11/3	ADZ	Absorbance illinitz error		
	1-1-		points or more within the absorbance limit range. (Except	
0),		en' AU	
11/1			that the continuous 8 points or	
Y			more are within the absorbance	
	5115	-	limit range.)	
76	DUP	Duplicate limit error	Duplicate limit error	
77	SEN	Sensitivity limit error	Sensitivity limit error	
78	CAL	Calibration failed.	Calibration failed due to the	
			effective points shortage	
79-81	Not used.			
82	STM	Mismatched sample type.	Measurement performed	
			applying the methods for the	
		· Mar	mismatched sample type for the	
		C.	sample.	
83	CLT	Mismatched lot number of the reagent	An error occurs when each of the	
		at the calibration.	lot numbers for both R1 and R2	
		10	reagents at measurement is not	
		2.	matched with that at the	2.
		0. 70.	calibration.	V 0.
84	CLM	Mismatched lot number of the reagent	An error occurs when the	0210302:3
		at the calibration.	reagent with the lot number at	01 00
	. (DV. CO.	preparing calibration is not	Or. CA.
	6		placed in the Reagent container.	1
	70.	.01	The error occurs when the auto	
	00,	74		X
	1 6	U*	number change of the reagent.	O.
3	19	<u> </u>	No measurement performed.	
u_{II}			WI. Fr	
0,	_\(\mathcal{O}\)		100	
	120		541. 14	
(0)			2. 50	
ENER			Shinwill	

5. Rerun result code

Code	Description
00	Sample volume was normal at the first result
01	Sample volume was normal at the rerun result
10	Sample volume was low at the first result
11	Sample volume was low at the rerun result
20	Sample volume was high at the first result
21	Sample volume was high at the rerun result

Shirmha CE	01 Sa 10 Sa 11 Sa 20 Sa 21 Sa	-	first result rerun result result in result it result un result	103 02:32:3
6.	01 Sa 10 Sa 11 Sa 20 Sa 21 Sa	mple volume was normal at the mple volume was low at the first mple volume was low at the rerumple volume was high at the first mple volume was high at the rerumple volume was high at the rerumple volume was high at the rerumple was high at the rerumple # 1 to 10	first result rerun result result in result it result un result	103 02:12:
6.6	10 Sa 11 Sa 20 Sa 21 Sa	mple volume was low at the first mple volume was low at the rerumple volume was high at the first mple volume was high at the rerumple volume was high at the rerumple was 1 to 10	rerun result result in result it result un result	10302:12
6.	11 Sa 20 Sa 21 Sa	mple volume was low at the rerumple volume was high at the first mple volume was high at the rerumple volume was high at the rerumple # 1 to 10	result in result it result un result	10302:27
6.0	20 Sa 21 Sa	mple volume was high at the firs mple volume was high at the rere e # 1 to 10	in result it result un result	10300.17
6.	21 Sa	mple volume was high at the rer e # 1 to 10	un result	103
6.6	OC flag cod	e # 1 to 10	un result	1,000
6.	QC flag cod Description	-	(-)	, C
503	Description 1	Data!!a	V 10 ,	_ \C
22	1	Details	QC flag code	2.
22		Current result exceeds 2SD	00: Normal, 01: Warning, 02: Error	
A 10	2	Current result exceeds 3SD	00: Normal, 01: Warning, 02: Error	
.10" 67	3	Current result exceeds 4SD	00: Normal, 01: Warning, 02: Error	
10	4	Last two results exceed 2SD range	00: Normal, 01: Warning, 02: Error	
JRU.	5	2 results out of 3 last results exceed 2SD.	00: Normal, 01: Warning, 02: Error	
_	6	Range for a defined period exceeds 4SD.	00: Normal, 01: Warning, 02: Error	
	7	Any 3 results for a defined period exceed 1SD.	00: Normal, 01: Warning, 02: Error	
	8	Any 4 results for a defined period exceed 1SD.	00: Normal, 01: Warning, 02: Error	
	9	Last 10 results higher or	00: Normal, 01: Warning (higher),	
		lower than mean.	02: Error (higher), 03: Warning	
		Λ.	(lower), 04: Error (lower)	
	10	Last 7 results trend	00: Normal, 01: Warning	
		0. 10	(increasing), 02: Error (increasing),	
		30	03: Warning (decreasing), 04: Error	2
		2.	(decreasing)	
	,03	Last 7 results trend	(increasing), 02: Error (increasing), 03: Warning (decreasing), 04: Error (decreasing)	10302:11
,6	105/10	0.	10/03	1,000
20	ECIM		20° EC	le.
Why OEL	~		Why OELL	
HI. IRUM			ShirIRUM	
- ÇV			ÇV.	23

3.8 C: Comment Record

8	C: Comment	Reco	ra	C_{M}	O.C.		
F N		on reco ormatio	rd, Order re n record. 7	cord, Resul	t record, Scie	entific record, and t record will be one lev	el OZ.12.3
Field	Designation	Max.	Process	This	Omission	Process on	3
#		digits	upon	system		transmission from	
		Or.	reception	used/unus		Analyzer	(h. 50.
			from Host	ed			
1)	Record type	1	Abandoned	Used	Disapproved	Record type "C"	210
2)	Sequence	6	Abandoned	Used	Disapproved	Refer to "3.3.1".	X.C.
	number	O.				1/ /	J*
3)	Source of	1	Fixed to "L"	Used	Disapproved	Fixed to "1"	
.1	comment					W. C.	
4)	Text of	40	Refer to the	Used	Disapproved	Refer to the table below.	
100	comment		table below.		-X	11. 1/2	
5)	Type of	1	Refer to the	Used	Disapproved	Refer to the table below.	
(1)	comment		table below.			SO.	

Precedin	g Type of	Usage of comment text
message	comment	
patient	G	Abandoned
order	G	Reflect sample information. (*1)
result	-	Unused:
scientific	G	Abandoned
manufactur	re G	Abandoned
to 40 cha	016102103 0ELECTRIC	O2:12:35 CONT Shinning

Shinwha, 2016 102 103 02:12:36 CO. LTD Note 1: The number of characters to be checked in the [Patient information] screen: up

3.9 **Q: Request Information Record**

2)		digits	upon reception from Host	system used/unus ed		transmission from Analyzer	02:
2)	Record type	1/ 🔍	Abandoned	Used	Disapproved	Record type "Q"	Y
	Sequence number	1	Abandoned	Used	Disapproved	"1"	
3)	Starting Range ID #	12	Abandoned	Used	Disapproved	Sample ID Fixed to "ALL" for batch.	
4)	Ending Range ID #	0	-	Unused	- 10	12 ELLE	
5)	Universal Test	0	-	Unused	-110,	HO	
5)	Nature of Request Time Limits	0	-	Unused	FUR	-	
7)	Beginning Request Results Date and Time	0	-	Unused	-	-	
8)	Ending Request Results Date and Time	0	-	Unused	TIAL	-	
9)	Request Physician Name	0	- 39	Unused) <u>.</u>	-	
10)	Request Physician Telephone Number	0	40.	Unused	-	-	02
11)	User Field # 1	0		Unused	-	- 10"	
12)	User Field # 1	0	<u>-</u>	Unused	-	- 2	رO
13)	Request Information Status Code	1	Abandoned	Used	Disapproved	Fixed to "N"	
JRUN'S	ELEC				Shirmh	NO ELECTRIC	

L: Message Terminator Record 3.10

Field #	Designation	Max. digits	Process upon reception from Host		Omission	Process on transmission from Analyzer
1)	Record type	1	Abandone	d Used	Disapprov	ed Record type "L"
2)	Sequence number	1/2	Abandone	d Used	Disapprov	ed "1"
3)	Termination code	0	40	Unused	-	- 000
ield	S: Scientific re	707	rocess	This	Omission	Process on
#	di	gits u	pon	system		transmission from
1	Was Ely		eception rom Host	used/unus ed		Analyzer
						AY

S: Scientific record 3.11

	Field #	Designation	Max. digits	Process upon reception	This system used/unus	Omission	Process on transmission from Analyzer	
	1	11. X.		from Host	ed		WILL VE	
	1)	Record type	1	Abandoned	Used	Disapproved	Record type "S"	
9	2)	Sequence number	1	Abandoned	Used	Disapproved	"1"	
	3)	Analytical Method	0	-	Unused	-	₹o.	
	4)	Instrumentation	0	-	Unused	-	-	
	5)	Reagents	0	-	Unused	-	-	
	6)	Units of Measure	0	-	Unused	-	-	
	7)	Quality Control	0	-	Unused	-	-	
	8)	Specimen Descriptor	0	-	Unused		IAL	
	9)	Reserved Field	0	-	Unused	- 24	-	
	10)	Container	0	-	Unused	OV	-	
	11)	Specimen ID	0	-	Unused	.(//	-	20
	12)	Analyte	0	- 0	Unused	67,	-	0.2
	13)	Result	0		Unused	-	-	
	14)	Result Units	0	- 2	Unused	-	-	2.
	15)	Collection Date and Time	0	3	Unused	-	-	30. (1)
	16)	Result Date and Time	0	.00	Unused	-	- 102	000
	17)	Analytical Preprocessing Steps	0		Unused	-	- 20161	03 02:12:39
	18)	Patient Diagnosis	0	-	Unused	-	Mai CLE	
	19)	Patient Birthdate	0	-	Unused	-	14, 70 p	
C	20)	Patient Sex	0	-	Unused	- 4	7)	
	21)	Patient Race	0	-	Unused	-	- 114	

3.12 M: Manufacturer information record

Shinnha 2016 102 103 02:12:39 CONFIDENTIAL Shinnha 2016 102 103 CO. LTD. CONFIDENTIAL

The manufacturer information record can be sent following the records below: Patient information record, Test order record, Result record, Scientific record, and Comment record. The level of the Manufacturer information record will be one level higher than the previous level.

	Field #	Designation	Max. digits	Process upon reception from Host	This system used/unus ed	Omission	Process on transmission from Analyzer
	1)	Record type	1	Abandoned	Used	Disapproved	Record type "M"
	2)	Sequence number	1	Abandoned	Used	Disapproved	"1"
Shinnin	JHC 13.5	ELECT				Shirwhi	NO ELECT

Shinwha, 2016 102 103 02:12:39 CONFIDENTIAL Shinwha, 2016 102 103 02:17:17. Shinwha, 2016 102 103 02:12:35.
Shinwha, 2016 102 FEET RICCO. LTD Shinnha, 2016 102 103 02:12:39 CONFIDENTIAL
Shinnha, 2016 102 103 02:17.D. CONFIDENTIAL Shirwha, 2016 102 103 02:12:36
Shirwha, 2016 102 FEE TRIC

Chapter 4 Communication mode

The following table describes the test ordering functions for each communication mode.

Mode/Status	٠0٠		Order	7.	Test results			
-22		Local	Batch	Real time	Local	Batch	Real time	
On Line Real time	During RUN	Normal and Emergency	- 10, A	Inquire orders for normal	Search, edit, and printout	Disapproved	Send result of normal or	
21 0	.5	samples can be entered	21, 100	samples by one sample.	available.		emergency samples to	
10, 0		manually. Test orders can	10, 0	Emergency samples can			Host automatically by one	
61 10		be edited.	61 10	only be handled locally.			sample.	
1 15	Stand-by	Normal and Emergency	- 167	-	Search, edit, and printout	Send test results to Host by	No action.	
.()		samples can be entered			available	selecting "Host" as		
		manually. Test orders can				destination.		
		be edited.						
On Line Batch	During RUN	Normal and Emergency	-	-	Search, edit, and printout	Disapproved	Send result of normal or	
(with a capability of		samples can be entered			available.		emergency samples to	
real time result		manually. Test orders can					Host automatically by one	
transmission to the		be edited.					sample.	
Host.)	Stand-by	Normal and Emergency	Acquire test orders for	-	Search, edit, and printout	Send test results to Host by	No action.	
		samples can be entered	normal sample from Host		available.	selecting "Host" as		
		manually. Test orders can	by clicking on the [Acquire]			destination.		
		be edited.	button.					
Off Line	During RUN	Normal and Emergency	-	-	Search, edit, and printout	-	-	
		samples can be entered			available.			
		manually. Test orders can						
		be edited.						
	Stand-by	Normal and Emergency	-	- 1	Search, edit, and printout	-	-	
	C. P.	samples can be entered		W CL	available.			
	V ().	manually. Test orders can		O. 10				
	~ (V)	be edited.		77 .CN				
transmission to the Host.)	During RUN	be edited. Normal and Emergency samples can be entered manually. Test orders can be edited. Normal and Emergency samples can be entered manually. Test orders can be edited. Normal and Emergency samples can be entered manually. Test orders can be entered manually. Test orders can	normal sample from Host by clicking on the [Acquire]	- CMT FIDENTIAL	search, edit, and printout available. Search, edit, and printout	selecting "Host" as	sample.	

Note:

- An emergency sample should be handled locally not via Host.
- The results for normal, emergency, online, and QC samples can be sent to Host.
- All results obtained at Off Line, Batch, and Real Time modes will be stored in one database.
- The batch mode is a batch mode with a capability of real time result transmission to the Host.

Shinwha. 2016/02/03 02:12:39 CONFIDENTIAL Shinwha. 2016/02/03 02:12:39 CONFIDENTIAL Shinwha. Shinwha, 2016/02/03 02:12:39 CONFIDENTIAL Shinwha, 2016/02/03 02:17.17. Shinnha 2016 102 103 02:12:39 CMFIDENTIAL
Shinnha 2016 102 103 02:12:39 CONFIDENTIAL

Shinnha 2016 102 103 02:12:39 CMFIDENTIAL

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Chapter 5 Communication sequence

5.1 Confirmation of connection sequence

Connection confirmation at beginning of each round. (On Line 5.1.1 Batch mode/Real time mode)

Analyzer will check communication status with Host at beginning of each round. This is to ensure the communication condition prior to an order inquiry of samples at measurement. For the Host side, communication status confirmation is required at beginning of each round.

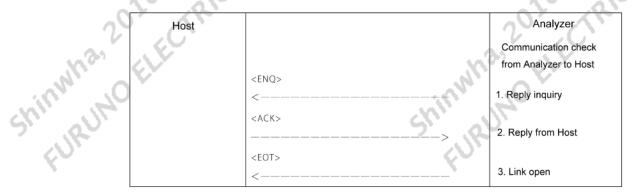


Figure 5.1-1

antinues fi ed with the rot When reply from the Host is <NAK> or no response, Analyzer will re-try up to 6 times. If <NAK> or no reply continues for 6 times, Analyzer will generate error message and will not proceed with the round.

5.2 **Batch sequence**

Batch transmission of result to Host 5.2.1

Host	20, 10,	Analyzer 1. Message Header Record
1051	H \^& Analyzer 20010111055300 <cr></cr>	Allalyzei
0	240-2	Message Header Record
.61	P 1 PID2734 Patient Name 19630501 M Race1 Physician Name 1234567890123 1 CR>	2.Patient Information Record
0,	0 1 001 ^^^1 01 <cr></cr>	3. Test Order Record
	C 1 I TestOrder1 G <cr></cr>	4. Comment Record
DELE ELE	R 1 ^^^1 15.265 mg/ml 20010110121530 <cr></cr>	5. Result Record
	O 2 001 ^^^3 01 <cr></cr>	6. Test Order Record
	R 1 ^^3 18.052 mg/ml 20010110121830 <cr></cr>	7. Result Record
	P 2 PID2738 Patient Name 19870501 M Race1 Physician Name 1234567890153 1 <cr></cr>	8.Patient Information Record
	O 1 890051 ^^^5 01 <cr></cr>	9.Test Order Record
	C 1 I TestOrder2 G <cr></cr>	10.Comment Record
	R 1 ^^^5 5.265 mg/ml 20010110151530 <cr></cr>	11. Result Record
	(snip)	
	P 9 PID2755 Patient Name 19870501 M Race1 Physician Name 1234567890553 1 <cr></cr>	12. Patient Information Record
	0 1 8900171 ^^^37 01 <cr></cr>	13. Test Order Record
	C 1 I TestOrder3 G <cr></cr>	14. Comment Record
	R 1 ^^^37 0.265 mg/ml 20010110171530 <cr></cr>	15. Result Record
	L 1 <cr></cr>	15. Result Record 16. Message Terminator Record
	103	Tresord 0 ?
. 0	2 O	21 (0
61	Figure 5.2-1	

Figure 5.2-1

Note:

- Comment information can be omitted.
- There can be multiple messages of test order and result for one patient information.
- Result record with error flag is not transmitted when it is set not to transmit result record when error occurred.

Inquiry to Host for order and response 5.2.2

The following is an example of communication when test order acquisition operation was done at test ordering screen at On Line Batch mode. The test order acquired will be added or overwritten to the existing order after it is confirmed and edited.

	Host	0.	Analyzer	0
	.03		Inquiry from Analyzer to Host	
	2	 H \^& Analyzer 20010111055300 <cr></cr>	Message Header Record) 15
	16101 BICC	<	Timessage neader Record	
Shinnha, 20	10 RIC	Q 1 ALL N <cr></cr>	Request Information Record	
2.7	SC,	L 1 <cr></cr>	Message Terminator Record	
Muss	Response from Host	Mices	ELL	
OLA, WINE	4. Message Header Record	H \^& Host 20010111055303 <cr></cr>	0	
Su. Bri	5.Patient Information Record	P 1 PID2734 Patient Name 19630501 M Race1 Physician Name 1234567890123 1 <cr></cr>		
Ło,	6.Test Order Record	0 1 001 ^^^01\^^^03 01 <cr></cr>		
, and the second	7. Comment Record	C 1 I TestOrder1 G <cr></cr>		
	8. Patient Information	P 2 PID2738 Patient Name 19870501 M Race1 Physician Name 1234567890153 1 CR>		
	Record 9. Test Order Record	O 1 890051 ^^^05 01 <cr></cr>		
	10. Comment Record	C 1 I TestOrder2 G <cr></cr>		
		(Snip)		
	11. Patient Information	P 9 PID2755 Patient Name 19870501 M Race1 Physician Name 1234567890553 1 <cr></cr>		
	Record 12. Test Order Record	O 1 8900171 ^^37 01 <cr></cr>		0
	13. Comment Record	C 1 I TestOrder3 G <cr></cr>		2.0
			- 1	,
	Record		-30	
	0/0-		2/0-	1.5
	100, 0	Figure 5.2-2	100,0	,
	16, 010		26, 510	
20			0	
Wa.		Man	elle	
:UN. 10	~	inn'	0	
SUI. SOLL		Shi July	b	
EUK		EUK		
Shinwha. 20		*	OFFIECTRIC CO.	

Figure 5.2-2

5.3 Real-time sequence

Real-time inquiry to Host for one sample and its response 5.3.1

•	uiry to Host for one sample and into the control of	,: b
	01. 0.	O'L.
Host	3	Analyzer
-2	0.00	Inquiry from Analyzer to Host
6/0"	H \^& Analyzer 20010111055300 <cr></cr>	1. Message Header Record
2030	Q 1 91000000001 N <cr></cr>	Request Information Record
31 150	L 1 <cr></cr>	Message Terminator Record
Response from Host		Why OEL
4. Message Header Record	H \^& Host 20010111055303 <cr></cr>	140
5. Patient Information Record	P 1 PID2734 Patient Name 19630501 M Race1 Physician Name 1234567890123 1 CR>	URU
6. Test Order Record	0 1 91000000001 ^^^01\^^^03 01 <cr></cr>	Y
7. Comment Record	C 1 I TestOrder1 G <cr>></cr>	
8. Message Terminator	L 1 <cr></cr>	

Figure 5.3-1

Note:

- When there is no order for inquired sample, return order information with empty universal test ID field ("00").
- Shinnha, 2016 102 103 02:12:36
 Shinnha, 2016 102 103 02:12:36 • When rerun is not required at host rerun mode, return order information with empty universal test ID field ("00"). However, auto rerun is performed for the ιe, ι is set method which is set as auto rerun.
 - Comment information can be omitted.

5.3.2 Real-time transmission of result to Host for one sample

The result is transmitted to Host when result for a sample is obtained during run. transmission is performed on On-Line Real-time mode and On Line Batch mode.

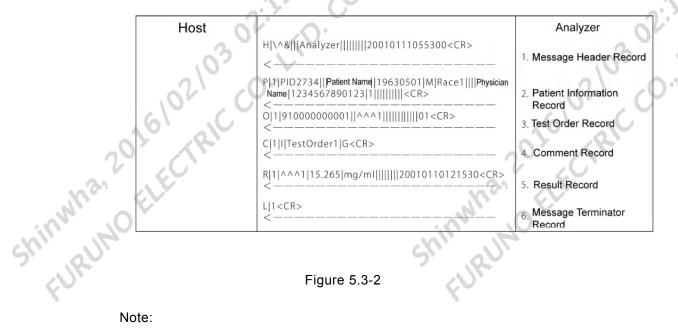


Figure 5.3-2

Note:

- Result is sent for one method per sample at a time.
- Universal test ID for test order record is transmitted as ID with the result.
- Jord is it ansmitted what arred. The lines "H" to "L" are not transmitted when it is set not to transmit result

Error handling 5.4

Transmission error 5.4.1

	sion error occurs, re-transmission of the m ssage. The buffered data will be saved a	it reception of higher level
Host	H \^& Analyzer 20010111055300 <cr> <</cr>	Analyzer 1. Message Header Record 2. Patient Information Record
2016	Physician Name 1234567890123 1 <cr> O 1 001 ^^^1 01<cr> C 1 TestOrder1 G<cr></cr></cr></cr>	3. Test Order Record
shinwha, 2016,	R 1 ^^^1 15.265 mg/ml 20010110121530 <cr< td=""><td>Comment Record Result Record</td></cr<>	Comment Record Result Record
FURLL	O 2 001 ^^^3 01 <cr> <</cr>	Test Order Record Result Record
	Physician Name 1234567890153 1	Patient Information Record Test Order Record
	R 1 ^^^5 5.265 mg/ml 20010110151530 <cr> <</cr>	10. Comment Record 11. Result Record
	P 9 PID2755 Patient Name 19870501 M Race1 Physician Name 1234567890553 1 <cr> <</cr>	12. Patient Information Record
	C 1 TestOrder3 G <cr> <</cr>	13. Test Order Record 14. Comment Record
		16. Message Terminator Record
Shirwha, 2016 C	Figure 5.4-1	Record 13. Test Order Record 14. Comment Record 15. Result Record 16. Message Terminator Record
Wha, OELE		gwha, OELEC
HI IRUM	Sin	III IRUM

	Error occurring	Re-transmission message	
	message) <u>.</u>	
	1)	1)	o'.
	2)	1) 2)	1
	3)	1) 2) 3)	2:
	4)	1) 2) 3) 4)	, O' ,
	5)	1) 2) 3) 4) 5)	103 02:31
	6)	1) 2) 3) 4) 5) 6)	
4	7)	1) 2) 3) 4) 5) 6) 7)	1610510 CO., 1
6	8)	1) 2) 3) 4) 5) 6) 7) 8)	6
100	9)	1) 8) 9)	10.010
00,	10)	1) 8) 9) 10)	, X.
· · · · · · · · · · · · · · · · · · ·	11)	1) 8) 9) 10) 11)	50.
1000 SO	12)	1) 8) 9) 10) 11) 12)	
MI. O.K.	13)	1) 12) 13)	Ç.
10, 70	14)	1) 12) 13) 14)	
lu. Oll	15)	1) 12) 13) 14) 15)	
Shinwha, 2016	16)	1) 12) 13) 14) 15) 16)	
(N)		50	•
*			

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Shinnha, 2016 102 103 02:12:39 CONFIDENTIAL

5.4.2 Reception error

A. Error during batch order Inquiry to Host and its response

When message 4) is not received for T1 time out time after transmitting 3), it will be handled as described on the table below. The messages 5) to 14) will be handled as an error if the message is not received for T2 time out time.



Figure 5.4-2

Error occurring message	Error handling
4) to 14)	Re-transmit 1), 2) and 3).

Perform re-transmission three times (Max.). When re-try over occurs, an alarm message is displayed.

T1: 10 sec., T2: 5 sec.

Error during real-time inquiry to Host for one sample and its response



Figure 5.4-3

Figure 5.4-3
Re-transmission message
Re-transmit 1), 2) and 3).
Re-transmission message Re-transmit 1), 2) and 3).
Shin
lin.
511

5.4.3 Abnormal data

A. Sequence Number

Abnormal data

Followings are	error handlings		
	J	s when abnormal data is found.	200
A. Sequence I	Number	12:3 OF.	22.3
•			02:30
B. Abnormal c	lata	0.,	05/03/0.1
Type of Message	Type of Field	Description	
Message Header	Delimiter	When invalid character is assigned, the system used default delimiters.	RIC
Patient Information	Patient ID	When received an existing patient ID with new information such as name, date of birth, gender, physician name, and SS#, all data process after the reception will be based on the new information.	EC.
Test order	Sample ID	Test orders with invalid sample ID will be ignored. No warning or error message is displayed.	
	Method	Test orders with methods such as not registered and reagent shortage will not be run. At reception, a warning message is displayed. Other available tests ordered together with invalid methods will be run.	
	A missin B. Abnormal of Type of Message Message Header Patient Information	A missing sequence numbers of the sequence numbers of	Type of Message Type of Field Description Message Header Delimiter When invalid character is assigned, the system used default delimiters. Patient Patient ID When received an existing patient ID with new information such as name, date of birth, gender, physician name, and SS#, all data process after the reception will be based on the new information. Test order Sample ID Test orders with invalid sample ID will be ignored. No warning or error message is displayed. Method Test orders with methods such as not registered and reagent shortage will not be run. At reception, a warning

5.4.4 Retry over

	Sequence	Process	
	Batch transmission of	Displays an error message on the screen. Other operation other	
	result to Host	than host communication will be continued.	
	Inquiry to Host for order	Displays an error message on the screen. Other operation other	
	and response	than host communication will be continued.	20
	Real-time inquiry to Host	Generates an alarm message. Transmit "No order" to Analyzer.	0.2
	for one sample and its	Other operation other than host communication will be continued.	1
	response	2:	2.
	Real-time transmission of	Generates an alarm message. The results that not transmitted to	20, XV
	result to Host for one	the Host will be saved in database. The saved results can be	(0,5 P)
	sample	transmitted manually from the result search screen.	
	Shinnha, 2016 PO	the Host will be saved in database. The saved results can be transmitted manually from the result search screen.	ECTRIC
J			

Chapter 6 Supplement

Supplement for "3.3.1 Sequence number" 6.1

Sequence number is generated by command type (H, P, and O).

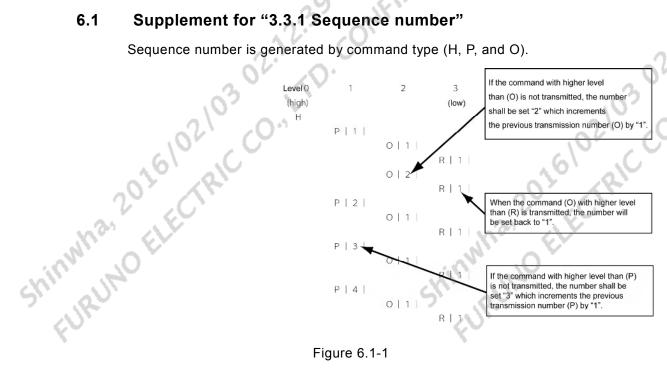


Figure 6.1-1

Chapter 7 Reference

Sample identification code 7.1

Sample	Identification	Digit	General	`O,	Details	4
category	code (SID)	No.	identification			2:
		0.	code (*)			200
Normal	xxxxxxxxxxxx	3 - 15	xxxxxxxxxxxx	xxxxxxxxxxxx	: Sample identification code	02
sample	<	2	x-nn1	nn	: Number of measurement	0302.
Normal	xxxxxxxxxxxx	3 - 15	xxxxxxxxxxx	xxxxxxxxxxxx	: Sample identification code	60
sample	70.	.01	x-nn1	nn	: Number of measurement	
(emergency)	20.0				20.	,
Normal	xxxxxxxxxxxx	3 - 15	xxxxxxxxxxx	xxxxxxxxxxxx	: Sample identification code	
sample	EL		x-nn1	nn	: Number of measurement	
(pediatric)	20			4	10, 70	
Online sample	xxxxxxxxxxxx	3 - 15	xxxxxxxxxxx	xxxxxxxxxxxx	: Sample identification code	
			x-nn1	nn	: Number of measurement	
Online sample	xxxxxxxxxxxx	3 - 15	xxxxxxxxxxx	xxxxxxxxxxxx	: Sample identification code	
(pediatric)			x-nn1	nn	: Number of measurement	
Emergency	99000xxx	8	99000xxx-nn1	xxx	: Sample identification code	
sample				nn	: Number of measurement	
Emergency	990009xx	8	990009xx-nn1	xx	: Sample identification code	
sample				nn	: Number of measurement	
(pediatric)				A 6		
QC sample	970000xx	8	990000xx-nn1	XX	: Sample identification code	
				nn	: Number of measurement	
Calibrator	98xxxxxy	8	98xxxxxy-nnm	xxxxx	: Reagent identification code	
			1.7	у	: Classification (1 to 7)	_ ^
			02.	nn	: Number of measurement	2
		2	- XV	m	: Number of repetition	3
Multi-Calibrat	950000xy	8	950000xy-nnm	x	: Set number	0302
or	,0	L'	0.,	у	: Classification (1 to 7)	(0)
	.61	(C		nn	: Number of measurement	()
	-03	101		m	: Number of repetition	
Diluted	93xxxxx0	8	93xxxxxy-nnm	xxxxx	: Reagent identification code	
Calibration	31			у	: Classification (1 to 7)	
	· V.			nn	: Number of measurement	

The general identification code corresponds to the SID with a suffix added depending on the number of measurements performed on that specific

sample.

• The general identification code is displayed on the SID column in the Round 02:12:35 screen.

7.2 Sample barcode label specifications

A. Barcode type

	Туре	SID digit	Check digit	Effective characters
		number	0.1	-2.
	UPC-A	10 digits ^{*1} or 11 digits ^{*2}	1 digit, Modulus 10	Numbers (0 to 9)
	UPC-E	6 digits*3	1 digit, Modulus 10	Numbers (0 to 9)
	JAN-13	12 digits	1 digit, Modulus 10	Numbers (0 to 9)
1/2	JAN-8	7 digits	1 digit, Modulus 10	Numbers (0 to 9)
Shinni	ITF	3 to 15 digits	1 digit, Modulus 10	Numbers (0 to 9)
	NW7 (CODABAR)	3 to 15 digits	1 digit, Modulus 16	Numbers (0 to 9), Symbols (-,\$,/,.,+)
	CODE39	3 to 8 digits	1 digit, Modulus 43	Alphanumeric (0 to 9, capital letters), Symbols (-,,&,/,+,%)
	CODE128 (set A)	3 to 15 digits	2 digits, Modulus 103	Alphanumeric (0 to 9, capital letters), Symbols (!,#,\$,%,(,),+,,/,:,,<,=,>,?,@,¥)
	CODE128 (set B)	3 to 15 digits	2 digits, Modulus 103	Alphanumeric (0 to 9, capital and small letters), Symbols $ (!,\#,\$,\%,(,),+,-,./,:,,<=,>,?,@,¥,),\{,\},\sim) $
	CODE128 (set C)	3 to 15 digits	2 digits, Modulus 103	Numbers (0 to 9)

a" for th.

الله "UPC-A" for th.

اله barcode, add "0" c When using CCD barcode reader and "UPC-A" for the sample barcode type, add "0" digit on the head of SID to make it

When using Laser barcode reader and "UPC-A" for the sample barcode type, use 11 digits for SID.

Shinwha, 2016 102 103 co., Life When using "UPC-E" for the sample barcode, add "0" on the head of SID to make it 7 digits in total.

Barcode structure

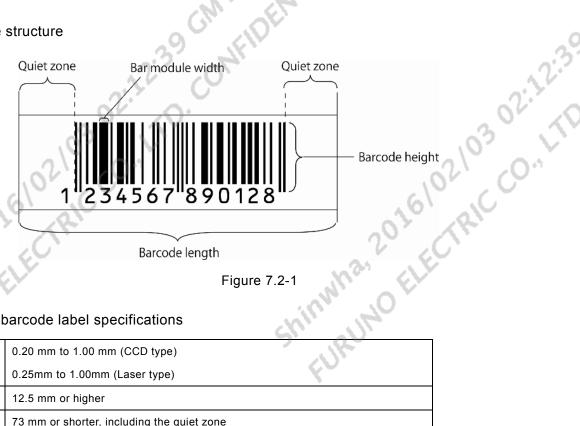


Figure 7.2-1

Sample barcode label specifications

Bar module width	0.20 mm to 1.00 mm (CCD type)	
60	0.25mm to 1.00mm (Laser type)	
Barcode height	12.5 mm or higher	
Barcode length	73 mm or shorter, including the quiet zone	
Quiet zone	4 mm or 10 times the length of the minimum module width, whichever the greater	
Printing	Black on the white background	
	Quality standard must comply with the ANSI MH10.8M standard.	
Barcode label location	Sample barcode label	7R1C CO.1.

7.3 User interface settings



7.3.1 **Host Communication setting**

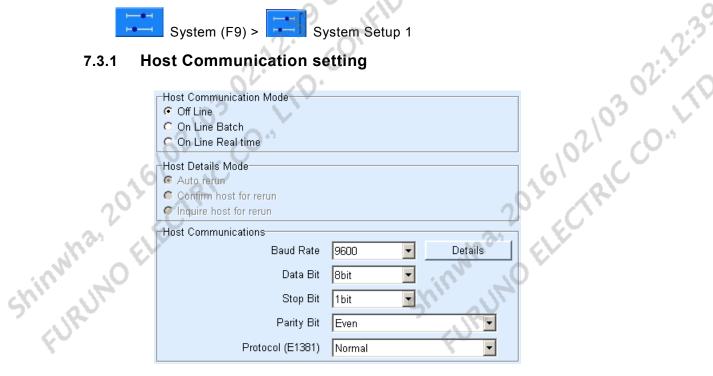


Figure 7.3-1

A. Host communication mode <default setting: Off Line>

Select host communication mode from the following:

Off Line

Perform measurement according to the analyzer settings without communication to the Host.

2. On Line Batch

Perform measurement according to the orders received from the Host. For the order inquiry to the Host, it needs to operate manually. The measurement results automatically send to the Host.

On Line Real time

Perform measurement according to the orders received from the Host. The analyzer reads the barcode labels on the Sample container and automatically inquires the orders to the Host for measurement. The measurement results automatically send to the Host.

Host details mode <default setting: Auto rerun>

Select the host details mode from the following: This setting is available only when the "On Line Real time" mode is selected.

Auto rerun

The order inquiry to the Host will not be executed

Confirm host for rerun

Host rerun will be executed only when the Host requires for rerun after the order inquiry.

3. Inquire host for rerun

Host rerun will be executed when the Host sends any responses after the order inquiry.

Host communications

Specify the communication setting to the Host.

Baud Rate < default setting: 9600> Select the rate (19200, 9600, 4800, 2400, 1200, 300) from drop-down menu.

Data Bit <default setting: 8bit>

Select the data bit (7bit or 8bit) from drop-down menu.

Stop Bit <default setting: 1bit>

Select the data bit (1bit or 2bit) from drop-down menu.

Parity Bit <default setting: Even>

Select the parity bit (none, even, odd) from drop-down menu.

Protocol (E1381) < default setting: Normal)

Select the protocol (normal or no handshake) from drop-down menu.

6. [Details] button

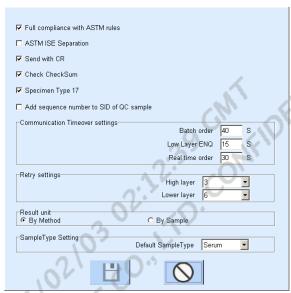


Figure 7.3-2

ASTM T Full compliance with ASTM rules <default setting: ON> Specify the transmission format to the Host whether to comply with ASTM rules. When ticking the checkmark ON, fully complied with ASTM rules. Under this setting, Rerun flags, QC measurement results, or QC flags will not be transmitted. Calculated test sends the results to the Host.

When not ticking the checkmark, not complied with ASTM rules. setting, Rerun flags, QC measurement results, or QC flags will be transmitted. ASTM ISE Separation <default setting: OFF> When ordering ISE tests from the Host, specify the format to separate ISE or

When Checkmark is ON, ISE will be separated into Na, K, and Cl.

- Send with CR <default setting: ON> Specify the text from the Host with CR or not. When ticking the checkmark ON, it sends with CR. When not ticking the checkmark it sends without CR.
- Check CheckSum <default setting: ON> Specify the checksum setting for data transmission. When ticking the checkmark ON, the checksum setting is active. When not ticking the checkmark, the checksum setting is not performed
- Specimen Type 17 <default setting: ON> Specify the command "O" on the 16th or 17th sample type field. When ticking the checkmark ON, use the 17th sample type field. When not ticking the checkmark, use the 16th sample type field.
- Add sequence number to SID of QC sample <default setting: OFF> This setting enables to identify the results when performing QC measurements several times for the specific sample or method at the same round. When ticking the checkmark ON, an added SID part is transmitted to the Host

When not ticking the checkmark, the added SID part is not transmitted to the Host when notifying Result record messages.

```
2010/09/29 10:03:55:fL-Recvi:<ENO>
                                         2010/09/29 10:03:55:[L-Send]:<ACK>
                                         2010/09/29 10:03:55:[H-Recv]:H|\^&|||Analyzer||||||| 20100929100355<CR>
                                         2010/09/29 10:03:55:[L-Send]:<ACK>
                                         2010/09/29 10:03:55:[H-Recv]:P[1]97000001|||||U|||||0|||||||||||^^^|<CR>
                                         2010/09/29 10:03:55:[L-Send]:<ACK>
                                         2010/09/29 10:03:55:[H-Recv]:C|1|1|G<CR>
                                         2010/09/29 10:03:55:[L-Send]:<ACK:
                                                                                                                   2016102103 02:12:3
2016102103 CO.LTD
When ticking the checkmark ON, → 2010/09/29 10:03:55;[H-Recv]; [O]1|97000001011||^^^002||20100929000000||0|||||05<CR>
When NOT ticking the checkmark, → 2010/09/29 10:03:55:[H-Recv]: 0|1|97000001| ^^^02||20100929000000||0|| | | |05<CR>
                                          2010/09/29 10:03:55:[L-Send]:<ACK>
                                         2010/09/29 10:03:56:[H-Recv]:C|1|| | G<CR>
                                         2010/09/29 10:03:56:[L-Send]:<ACK>
                                         2010/09/29 10:03:56:[H-Recv]:R|1|^^^02|-2045.96|||<||||||20100929100354 <CR>
                                         2010/09/29 10:03:56:fL-SendI:<ACK>
                                         2010/09/29 10:03:56:[H-Recv]:L|1<CR>
                                          2010/09/29 10:03:56:[L-Send]:<ACK>
                                           :010/09/29 10:03:56:[L-Recv]:<EOT>
```

Figure 7.3-3

Shirwha, 20' **Communication Timeover settings**

when notifying Result record messages.

- Specify the timeout setting.
 - Batch order:

Shinnha, 21

Specify the batch order to the Host from 1 to 60 sec

- <default setting: 40 sec.>
- Low Layer ENQ:

Specify the low layer ENQ from 1 to 60 sec.

<default setting: 15 sec.>

- Real time order:

Specify the data reception from 1 to 60 sec.

<default setting: 30 sec.>

Retry settings

Specify the number of each retry for high layer and lower layer.

High layer: select the number (1 to 6) from drop-down menu.

<default setting: 6.>

Lower layer: select the number (1 to 6) from drop-down menu.

<default setting: 3>

Result unit

Specify the result transmission unit.

Select "By Method" or "By Sample".

<default setting: By Method>

Sample Type Setting

Specify the default sample type when omitting the sample type in transmission message from the Host.

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Select (Serum, Urine, Plasma, or Others) from drop-down menu.

<default setting: Serum>



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