INNOVANCE PFA-200 System

Data Interface Manual – For IT Services Only
2021-10

SIEMENS Healthineers

1 Introduction

This chapter gives introductory information.

1.1 Target audience

This manual is for the following audiences:

- Siemens Healthineers service
- External IT service provider
- The customer's IT department

1.2 About this manual

This manual describes the transmission of information between the INNOVANCE® PFA-200® System and the laboratory information system (LIS).

1.3 Information for the customer's IT department

For an overview of the information for the customer's IT department, see the table below.

Chapter	Explanation	See
Technical specifications	This chapter describes the technical specifications and hardware requirements for the LIS connection.	(➔ Page 9 *Hardware requirements*)
Installing and connecting	This chapter describes how to install the software and how to connect the system to the LIS.	(➔ Page 10 *Installing and connecting*)
Configuring the LIS connection	This chapter describes how to select the required LIS option.	(➔ Page 11 *Configuring the LIS connection*)
Configuring the data interface for the PFA-100 RS232 mode	This chapter describes the configuration of the PFA-100 RS232 mode.	(➔ Page 12 *Configuring the data interface for the PFA-100 RS232 mode*)
Configuring the data interface for the ASTM RS232 mode	This chapter describes the configuration of the ASTM RS232 mode.	(➔ Page 18 *Configuring the data interface for the ASTM RS232 mode*)

Information for the customer's IT department

1.4 Orientation tips

	Indicates a hint Is used to provide information on how to avoid operating errors or information emphasizing important details
	Indicates the solution of a problem Is used to provide troubleshooting information or answers to frequently asked questions
●	Indicates a list item
✓	Indicates a prerequisite Is used for a condition that has to be fulfilled before starting a particular procedure
◆	Indicates a 1-step procedure or procedural steps to solve a problem
1 2 3	Indicate steps within procedures
➔	Indicates a link to related information as well as previous or next steps
→	Indicates the result of a procedural step or a procedure
Italic	Is used for references and for table or figure titles
Bold	Is used to identify window titles, menu items, function names, buttons, and keys, for example, the button **Enter**
Menu > Menu item	Is used for the navigation to a certain submenu entry
Orange	Is used to emphasize particularly important sections of the text

1.5 Service

Siemens Healthineers and its representatives are available to repair the system during customary local office hours. If service is required at any other time, contact Siemens Healthineers service or a local Siemens Healthineers representative. In the following, “Siemens Healthineers service” refers to both Siemens Healthineers service or any local representative authorized by Siemens Healthineers. Information about how to reach Siemens Healthineers service is provided when the system is installed, or visit siemens-healthineers.com to find contact information.

Siemens Healthineers will provide information about the availability and cost of updates.

The scope of agreed service is included in the service contract.

1.6 Warranty

Siemens Healthineers and its representatives guarantee that the system shows no defects after installation, and during operation if operated according to this manual. For more information on warranty, contact Siemens Healthineers service. The warranty is not valid for damage that occurs as a consequence of non-observance of this manual.

Repairs and servicing must only be carried out by persons authorized by Siemens Healthineers.

Only use the system as intended. If the system is not used as intended, Siemens Healthineers disclaims all liability for damage to the system.

1.7 Ordering information

Only use original Siemens Healthineers consumables, accessories, and spare parts. Order these only from Siemens Healthineers. For ordering information, see the Siemens Healthineers product catalog or contact Siemens Healthineers service.

1.8 Trademarks

Dade, INNOVANCE, and PFA-200 are trademarks of Siemens Healthineers Diagnostics Products GmbH or its affiliates.

All other trademarks are the property of their respective owners.

1.9 Manual version history

Manual			Software	
Version	**Date**	**Changes**	**Full version**	**Release version**
1.0	2010-12	First version	2.0	2
2.0	2017-06	Update	2.1.1	2
01	2021-10	Update	2.1.1	2

2 Safe handling

This chapter describes the intended use of the system and gives general safety instructions.

2.1 General safety information

The system has been inspected for technical safety before distribution. To maintain this status and to ensure hazard-free operation:

- Always follow the instructions in this manual and in the instruction manual of the system.

2.1.1 Operator qualification

Risk of death and serious injury due to lack of knowledge. To avoid this hazard:

- The system must be operated only by persons whose skills, knowledge, and practical experience qualify them to do so, and who have read and understood this manual.

2.1.2 Operational safety

Using cables that do not comply with the specifications can affect the transmission of information between the system and the LIS. To avoid this hazard:

- Only use the data cables specified, see (➔ Page 9 *Pin assignment analyzer/host computer*) .

Modifications of the system software can affect the operation of the analyzer. To avoid this hazard:

- Do not modify the system software, for example, do not update the operating system or install any software not authorized by Siemens Healthineers.

2.2 Safety messages

All safety messages must be observed to avoid hazardous situations which can result in death, injury, or damage to the equipment.

The following explains the signal words and their meanings.

Signal word	Meaning
WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury
CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury
NOTICE	Indicates a hazardous situation which, if not avoided, could result in potential damage to property

The following explains the structure of safety messages.

WARNING

This section states nature and source of the hazard.

This section states potential consequences of not avoiding the hazard. This section can be combined with the previous section.

◆ This section lists preventive actions to avoid the hazard.

2.3 Statutory provisions

The product bears a CE mark which certifies that the product meets the requirements of the following European directives:

- In vitro diagnostic medical devices Regulation (EU) 2017/746
- Directive on restriction of hazardous substances 2011/65/EU

Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

The product also meets the requirements of the following European directives:

- Directive on waste electrical and electronic equipment 2012/19/EU
- Battery Directive 2006/66/EC

The product has been developed, tested, and manufactured in accordance with IEC 61010-2-101, ISO 14971, IEC 61326-2-6, IEC 62304, and IEC 62366.

The product has been tested in accordance with IEC 61326-2-6. The product corresponds to CISPR 11 Class A regarding electromagnetic compatibility (EMC).

The product owner takes on the obligations arising from the national legislation about the operation of in vitro diagnostic medical devices.

3 Hardware requirements

The INNOVANCE PFA-200 System uses a unidirectional serial communication via one of the PC's serial ports.

The serial connection requires a null modem cable with a DB 9-female connector to the analyzer and a DB 9-female connector to the host computer.

The null modem cable must have the following pin assignment:

	DB 9 (Analyzer)	DB 9 (Host computer)
TxD - RxD	3	2
RxD - TxD	2	3
RTS - CTS	7	8
CTS - RTS	8	7
DTR - DCD/DSR	4	1 + 6
DCD/DSR - DTR	1 + 6	4
COMMON (Signal GND)	5	5
RI	9	9

Pin assignment analyzer/host computer

The RTS and CTS lines on the C side are connected to each other and are not used for hardware handshaking. The DSR and DTR lines are used to determine physical connection between the analyzer and the remote computer; to indicate that readiness to receive the DTR line is set high.

The RS-232 port settings are as follows:

Communication parameters	
Baud rate	9600
Parity	None
Data bits	8
Stop bits	1

RS-232 port settings

4 Installing and connecting

This chapter describes how to install the software and how to connect the system to the LIS.

4.1 Installing the data interface software

The data interface software is already installed on the system together with the system software.

4.2 Connecting the LIS

To connect the system with the LIS, proceed as follows:

1 Configure a data interface software which translates the data delivered by the INNOVANCE PFA-200 System into the syntax required by the LIS.

→ For detailed information about the syntax of the data provided by the INNOVANCE PFA-200 System, see the following chapters:

- For running the system in the PFA-100 RS232 mode, see (➔ Page 12 *Configuring the data interface for the PFA-100 RS232 mode*)
- For running the system in the ASTM RS232 mode, see (➔ Page 18 *Configuring the data interface for the ASTM RS232 mode*)

2 Switch off the analyzer and the host computer.

3 Connect the analyzer and the host computer via a null modem cable according to the specifications given in (➔ Page 9 *Hardware requirements*).

4 Switch on the analyzer and the host computer.

5 Enable the LIS option in the INNOVANCE PFA-200 Software, see (➔ Page 11 *Selecting the LIS option*).

5 Configuring the LIS connection

This chapter describes how to select the required LIS option.

To enable the ASTM RS232 option on your analyzer, contact Siemens Healthineers service.

For detailed information about the handling of the software functions, see the instruction manual of the system.

5.1 Selecting the LIS option

To select the LIS option in the INNOVANCE PFA-200 Software, proceed as follows:

1 Login as administrator.

2 Select the menu **Configure**.

3 In the menu Configure, tap **LIS Setup**.

→ The dialog **LIS Setup** is opened.

4 In the dialog **LIS Setup**, select the required LIS option.

5 Tap **Save**.

→ The setting is saved and the dialog **LIS Setup** is closed.

6 Configuring the data interface for the PFA-100 RS232 mode

In the following the syntax of the data, delivered by the INNOVANCE PFA-200 System, is described.

Based on the information given in this chapter, the data interface of the LIS must be configured to understand, evaluate and store these data.

The PFA-200 System transmits each result with a checksum. The format for the checksum line is **cs: nnnn<FS><CR>**.

It is the responsibility of the user to ensure that the data received by the host computer is accurate. To ensure this, the communication software used by the laboratory should have the capability to calculate the checksum value by adding up the transmitted characters one byte at a time including all characters **<CR>**and **<FS>**, starting with the first character of the header until the last character before the checksum line. The checksum is a two byte module 65536 value. Each line has a **<CR><FS>**at the end.

For checksum calculation, spaces must be included (e.g. "ID-Nr.:1234 ").

6.1 Transmission of patient results

6.1.1 Syntax of the patient results

There are 8 lines of characters in a patient result transmission. The syntax of each line is described in the following.

Line 1: Product model identification

Format:

PFA-200<LF><CR>

Line 2: Product software revision and serial number

Format:

REV. 9.99 S/N: 99999<LF><CR>

9.99	Software revision number
99999	Instrument serial number

Line 3: Date and time of result

Format options (depending on the settings by the administrator):

dd/mm/yyyy hh:mm xx<LF><CR>

mm/dd/yyyy hh:mm xx<LF><CR>

yyyy/mm/dd hh:mm xx<LF><CR>

dd/mm/yyyy hh:mm<LF><CR>

mm/dd/yyyy hh:mm<LF><CR>

yyyy/mm/dd hh:mm<LF><CR>

dd	Day of month
mm	Month of year

yyyy	Year
hh	Hour of day
mm	Minute of hour
xx	AM/PM if 12 hour time format was chosen

Line 4: Sample identification number

Format:

ID#: aaaaaaaaaaaa<LF><CR>

aaaaaaaaaaaa	User entered alphanumeric sample ID

Line 5: Test type identification

Format options:

Test Type: Collagen/EPI<LF><CR>

Test Type: Collagen/ADP<LF><CR>

Test Type: P2Y<LF><CR>

Line 6: Sample position and closure time

Format options:

SAMPLE A:

SAMPLE A: 999 Sec

SAMPLE A: >999 Sec

SAMPLE A: 999* Sec

SAMPLE A: >999* Sec

SAMPLE B:

SAMPLE B: 999 Sec

SAMPLE B: >999 Sec

SAMPLE B: 999* Sec

SAMPLE B: >999* Sec

A/B	Cartridge position
Sec	Seconds
>	Optional flag indicating closure time is greater than the value
999	Measured closure time
*	Optional flag indicating closure time is above or below the reference range

If there is no entry following **SAMPLE A:** or **SAMPLE B:**, this indicates that no closure time was measured.

Line 7: Error flags and information

The host system must be configured with a translation table to interpret the following flags.

Format options:

If no error flag is transmitted:

<LF><CR>

Otherwise, one of the following error conditions is transmitted:

Flow Obstruction<LF><CR>

Sample Depleted<LF><CR>

Maximum Syringe Travel<LF><CR>

Maximum Test Time<LF><CR>

Air Leak<LF><CR>

Processing Error<LF><CR>

Depending on the language settings in the INNOVANCE PFA- 200 INNOVANCE PFA-200 Software, the error flags will be transferred in the respective language.

For detailed information on errors flags, see the instruction manual of the system.

Line 8: Checksum

Format:

cs: 9999<LF><CR>

9999	Calculated checksum value

6.1.2 Example of a transmitted patient result

PFA-200

REV. PFA S/N: 011

05/06/2010 05:13 PM

ID# 4711

Test Type: Collagen ADP

SAMPLE A: Sample Air Leak

Sample Depleted

cs: 7664

The commands **<CR>** and **<LF>** are not included in a printout. If no error flag was transmitted, a patient result will comprise 7 lines only.

6.2 Transmission of quality control (QC) results

6.2.1 Syntax of QC results

There are 10 lines of characters in a quality control result transmission. The syntax of each line is described below.

Line 1: Product model identification

Format:

PFA-200<LF><CR>

Line 2: Product software revision and serial number

Format:

REV. 9.99 S/N: 99999<LF><CR>

9.99	Software revision number
99999	Instrument serial number

Line 3: QC identification

Format:

QC:<LF><CR>

Line 4: Date and time of result

Format options (depending on the settings by the administrator):

dd/mm/yyyy hh:mm xx<LF><CR>

mm/dd/yyyy hh:mm xx<LF><CR>

yyyy/mm/dd hh:mm xx<LF><CR>

dd/mm/yyyy hh:mm<LF><CR>

mm/dd/yyyy hh:mm<LF><CR>

yyyy/mm/dd hh:mm<LF><CR>

dd	Day of month
mm	Month of year
yyyy	Year
hh	Hour of day
mm	Minute of hour
xx	AM/PM if 12 hour time format was chosen

Line 5: Sample identification number

Format:

ID#: aaaaaaaaaaaa<LF><CR>

aaaaaaaaaaaa	User entered alphanumeric sample ID

Line 6: Test type identification

Format options:

Test Type: Collagen/EPI<LF><CR>

Test Type: Collagen/ADP<LF><CR>

Test Type: P2Y<LF><CR>

Line 7: Cartridge lot number

Format:

Lot Number: aaaaaaaaaaaa<LF><CR>

aaaaaaaaaaaa	User entered lot number of the cartridge

In case the same lot number is erroneously run with a second test type, this line will have the following format:

Lot Number: aaaaaaaaaaaa (AAA)<LF><CR>

aaaaaaaaaaaa	User entered lot number of the cartridge
AAA	Test type (EPI or ADP)

Line 8: Sample position and closure time

Format options:

SAMPLE A:

SAMPLE A: 999 Sec

SAMPLE A: >999 Sec

SAMPLE A: 999* Sec

SAMPLE A: >999* Sec

SAMPLE B:

SAMPLE B: 999 Sec

SAMPLE B: >999 Sec

SAMPLE B: 999* Sec

SAMPLE B: >999* Sec

A/B Cartridge position

A/B	Cartridge position
Sec	Seconds
>	Optional flag indicating closure time is greater than the value
999	Measured closure time
*	Optional flag indicating closure time is above or below the reference range

If there is no entry following **SAMPLE A:** or **SAMPLE B:**, this indicates that no closure time was measured.

Line 9: Error flags and information

The host system must be configured with a translation table to interpret the following flags.

Format options:

If no error flag is transmitted:

<LF><CR>

Otherwise, one of the following error conditions is transmitted:

Flow Obstruction<LF><CR>

Sample Depleted<LF><CR>

Maximum Syringe Travel<LF><CR>

Maximum Test Time<LF><CR>

Air Leak<LF><CR>

Processing Error<LF><CR>

Depending on the language settings in the INNOVANCE PFA-200 Software, the error flags will be transferred in the respective language.

For detailed information on errors flags, see the INNOVANCE PFA-200 System Instruction Manual.

Line 10: - Checksum

Format:

cs: 9999<LF><CR>

9999	Calculated checksum value

6.2.2 Example of a transmitted QC result

PFA-200

REV. PFA S/N: 001

QC:

05/06/2010 05:44 PM

ID# 123456

Test Type: Collagen ADP

Lot Number: 5595426 (ADP)[1]

SAMPLE A: Sample Air Leak

cs: 9761

The commands **<CR>** and **<LF>** are not included in a printout. If no error flag was transmitted, a QC result will comprise 9 lines only.

7 Configuring the data interface for the ASTM RS232 mode

7.1 Protocol

In the following the syntax of the data, delivered by the INNOVANCE PFA-200 System, is described.

Based on the information given in this chapter, the data interface of the LIS must be configured to understand, evaluate and store these data.

7.1.1 ASTM mode

In the ASTM mode communication proceeds by means of frames. These are each unique and defined for only one communication direction. The protocol was programmed according to the ASTM guidelines. See the documents ASTM E1394-97 and E1381-95 for further information.

Term	Description
ASTM	American Society for Testing and Materials Protocol for the transfer of data between analyzers and computer systems of the ASTM. See also ASTM-High and ASTM-Low below.
ASTM-High	ASTM, Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems, E1394-97 of March 1998. ASTM E1394-97 was replaced by NCCLS LIS2-A2. This document uses the more common ASTM field numbering system of E1394-97.
ASTM-Low	ASTM, Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, E1381-95 of January 1996. ASTM E1381-95 was replaced by NCCLS LIS1-A.

Explanation of term

7.1.2 Primary/secondary communication

The analyzer sends data to the host and the host responds. The host does not make any queries. Asynchronous sending of job lists by the host is not recommended.

7.1.3 Acknowledgment of receipt of a frame

Every receipt of a record must be confirmed with a positive (ACK) or negative (NAK) response.

7.1.4 Start and end of frame

In order to define the start and end of a frame, each frame starts with STX and ends with ETX, then CR and LF. If it is a continuation frame, it ends with ETB.

7.1.5 Frame number (FN)

For frame numbers between 0 to 7. As soon as the transmission phase begins (see ASTM Low) the frame number is set to 1 and increased by one for every subsequent frame that is sent. When the value 7 has been reached, the frame number takes a value of zero and is then increased in number again.

7.1.6 Continuation (ETB)/frame length

Messages are sent in frames. The frames do not exceed a length of 247 characters including checksum and record start and record end characters. If the message consists of more than 240 characters, it will be divided up into as many frames as necessary. In order to differentiate the continuation frame from a normal frame, ETB is sent instead of ETX.

7.1.7 Useful data field

The actual information is sent in the useful data field. There, any characters apart from STX, ETX, ACK, NAK, LF, CR, ETB, EOT or ENQ can be used.

7.1.8 Checksum

To increase the reliability of the data transmission, according to the ASTM standard, a checksum calculation on the contents of the frame is performed: frame number, record and the characters ETB or ETX. This checksum (abbreviated by C1C2) is then inserted in the frame. It is appended to the data field but comes before the end of the data field as indicated by CR LF.

7.1.9 Calculation of the checksum

- Adding of the ASCII values of all characters from the frame number up to the end character ETX
- Form result modulo 256
- Display the result hexadecimally

7.1.10 Structure of the record

Every record has the following general structure:

For a continuation frame: <STX> FN Record <ETB> C1 C2 <CR><LF>

For an end frame: <STX> FN Record <ETX> C1 C2 <CR><LF>

ASCII code	HEX value	DEC value	Description
STX	02	2	Start of frame
ETX	03	3	End of frame
ACK	06	6	Positive confirmation of receipt
NAK	15	21	Negative confirmation of receipt

ASCII code	HEX value	DEC value	Description
CR	0D	13	Carriage return
LF	0A	10	Line feed
ENQ	05	5	Request
EOT	04	4	End of transmission
ETB	17	23	Continuation frame

Control characters

7.2 Message structure

In the following, all records used in the ASTM protocol are described.

First the structure of the respective record is explained by means of a detailed description of each individual field. Since in contrast to other protocols there is no field length limitation with ASTM, the field lengths from the INNOVANCE PFA-200 System are not checked. The lengths given below are guidelines in order to ensure compatibility with other systems.

For the same reason, using empty spaces or zeros as fillers is not necessary. Neither are there any fields that must be filled from the right (right aligned).

Finally, examples for the processing are given. Only the records themselves are displayed (STX/ETX, checksum...) without the frame.

7.2.1 Analyzer to host

When data are sent to the host the following structure basically applies:

H-record

P-record

O-record

R-record

C-record

L-record

and/or for requests:

H-record

Q-record

L-record

7.2.2 Host to analyzer

Data sent to the analyzer must be sent structured as follows:

H-record

P-record

O-record

L-record

and/or for the negative confirmation of requests:

H-record

Q-record

L-record

7.2.3 H-record and L-record

A predefined structure must be kept to when sending messages from the host to the analyzer and vice versa. At the start of transmission of the message a so called Header record (H-record) must be sent and the last record must be a L-record (last record which is also called a message termination record).

For all ASTM records sent to the analyzer trailing delimiters (e.g.I) do not have to be sent.

7.2.4 Combining several assays of a sample

If several assays one after the other are sent to the analyzer by the INNOVANCE PFA-200 System software (viewer) and these assays belong to the same sample they are combined within a P-record. The structure then looks like this:

H-record

P-record

O-record1

R-record1.1

(C-record1.1)

O-record2

R-record2.1

(C-record2.1)

O-record3

R-record3.1

...

L-record

7.2.5 Sending individual queries (requests)

Only one query at a time is sent from the analyzer to the host. When a record has been responded to by the host with a Q-record or with a P-record and the accompanying O-record(s), or a timeout occurs, the next one will be sent.

7.2.6 Comment records (C-records)

Comment records can be sent at any point between two records of a message. The number of C-records after one another and within a message is thereby unimportant. Comments by the host are ignored by the analyzer. The analyzer always inserts a comment record after the R-record containing an error flag, even if the flag is zero.

7.3 Header record

ASTM field[a)]	Field name	Transmitted to host	Received from host	Description
7.1.1	Record Type	H	H	Analyzer transmits upper case characters, receives upper case.
7.1.2	Delimiters	(@)[b)]	(@)	The four standard delimiters are transmitted in this field: **|** Field **** Repeat **^** Component **&** Escape
7.1.5	Sender Name or ID	PFA-200 nnnnnnnnnn	(@)	This field contains the ID of the sending application: To host, this field will contain the identity of the analyzer which performed the analysis (PFA-200-nnnnnnnnnn) where nnnnnnnnnn is the serial number of the analyzer.
7.1.12	Processing ID	(@)	(@)	The following codes are used: **P** Production. If the field is blank, this is the default. **Q** Quality Control/Regulatory The following codes are not supported: **T** Training (data not stored) **D** Debugging (data not stored)
7.1.13	Version Number	LIS2-A3	LIS2-A3	Version of the standard this protocol implements.
7.1.14	Date and Time	(@)	(@)	This field contains the message transmission time (YYYYMMDDHHMMSS).

Structure of the header record

a) Field numbers not listed in this table are not supported. If transmitted from the host they will be ignored and they will always be null when transmitted from the analyzer.
b) Indicates supported field for identified communication direction.

Examples:

Header record: analyzer to host

H|\^&|1||PFA-200-IN000950|||||||P|LIS2-A3|201705324083831<CR>

Header record: host to analyzer

H|\^&|1||Hospital-LIS|||||||P|LIS2-A2|20100727121212<CR>

7.4 Patient record

ASTM field[a)]	Field name	Transmitted to host	Received by host	Description
8.1.1	Record Type	P	P	The analyzer accepts upper case characters. Multiple patient records under a single header record are not supported.
8.1.2	Sequence Number	(@)[b)]	(@)	Sequential number starting with 1 and continuing until the last patient in the message.
8.1.4	Laboratory Patient ID	(@)	(@)	This field may be a maximum of twenty (20) alphanumeric characters. This data from the LIS will be saved in the database of the analyzer.
8.1.6	Patient Name	(@)^(@)^(@)^^	(@)^(@)^(@)^^	This field contains 5 components as follows: Last Name (A20) First Name (A20) Middle Initial (A1) Title (Ignored) Suffix (Ignored) This data from the LIS will be saved in the database of the analyzer.
8.1.26	Location	(@)	(@)	The analyzer may optionally handle this field. This data from the LIS will be saved in the database of the analyzer.

Structure of the patient record

a) Field numbers not listed in this table are not supported. If transmitted from the host they will be ignored and they will always be null when transmitted from the analyzer.

b) Indicates supported field for identified communication direction.

Examples:

Patient record: analyzer to host: P|1||P123456||Last^First^M^^2nd|||||||||||||||||||| Location|||||||||<CR>

Patient record: host to analyzer: P|1||P123456||Last^First^M^^2nd|||||||||||||||||||| Location|||||||||<CR>

7.5 Order record

ASTM field[a)]	Field name	Transmitted to host	Received by host	Description
9.4.1	Record Type	O	O	Analyzer receives upper case characters.
9.4.2	Sequence Number	(@)[b)]	(@)	Sequential number starting with 1 and incrementing for each record transmitted.
9.4.3	Specimen ID	(@)	(@)	The analyzer accepts the Specimen ID received in this field from the LIS and returns it unchanged to the LIS. This field is a maximum of 20 alphanumeric characters. If sample barcoding is in use, there must be a character by character match between the barcode and this number. The use of this field is required.
9.4.5	Universal Test ID	^^^(@)	^^^(@)	This field will have 4 components. The first three components are not supported. The fourth component will contain the Manufacturers Test Code. For Test Codes see next table.
9.4.6	Priority	Not supported, will always be null when transmitted by the analyzer.	(@)	The following codes are used: **S** Stat **A** As Soon As Possible **R** Routine If no priority is assigned **R** will be assumed as default. The analyzer accepts the LIS assigned priority and returns it unchanged. Note: The analyzer does not have the ability to alter its test processing activities based on priority. An analyzer retransmission will have a null priority.

ASTM field[a)]	Field name	Transmitted to host	Received by host	Description
9.4.12	Action Code	(@)	(@)	The following codes are used: **N** New - Used to identify new test orders **Q** QC - Treat as QC specimen Note: This must be **Q** for QC samples, otherwise it is ignored when transmitted by the LIS host. Will always be Q or N when transmitted by the analyzer. If no action code is assigned or anything other than **Q** is received, **N** will be assumed as default. The following codes are not supported: **C** Cancel Order - Used to cancel a previously downloaded Order, or reject a request from the host. **A** Add - Used to add a Test(s) to an existing specimen.
9.4.16	Specimen Descriptor	W	Not supported, will always be null when transmitted by the analyzer	This field contains the component Specimen Type. The analyzer only supports 1 specimen type: **W** Whole Blood If no specimen descriptor is assigned, **W** will be assumed as default.
9.4.26	Report Type	Not supported, will always be null when transmitted by the analyzer	(@)	The following codes are sent by the analyzer: **F** Final results (not supported) **P** Preliminary results (not supported) The following codes are sent by the LIS host: **Q** Response to query (this record is a response to a request-information query) **Y** No order on record (in response to query) **O** Order record - User asking that analysis be performed (not supported)

Structure of the order record

a) Field numbers not listed in this table are not supported. If transmitted from the host they will be ignored and they will always be null when transmitted from the analyzer.

b) Indicates supported field for identified communication direction.

The following Test Codes are used:

Test code	Test
ADP	Collagen ADP
EPI	Collagen EPI
P2Y	P2Y

Examples:

Order record: analyzer to host: O|1|S123456||^^^ADP||||||||||W|||||||||||||||<CR>

Order record: host to analyzer: O|1|S123456||^^^ADP|R|||||N||||W|||||||||Q||||||<CR>

7.6 Result record

ASTM field[a)]	Field name	Transmitted to host	Received from host	Description
10.1.1	Record Type	R	Not supported, if transmitted by LIS host it will be ignored	The analyzer transmits upper case characters. Result records are never accepted from a LIS or host system.
10.1.2	Sequence Number	(@)[b)]		Sequential number starting with 1 and incrementing for each record transmitted.
10.1.3	Universal Test ID	^^^(@)		This field will have 4 components. The first 3 components are not supported. The fourth component will contain the Manufacturers Test Code. See table before for test codes.
10.1.4	Data Measurement	(@)		This is a 4 character alphanumeric field (A4). Normally this will be a number indicating Closure Time, but a > may precede the value under certain conditions. If this is the case, there will be a corresponding Comment Record to explain the condition causing the > annotation. See table before for comment codes.
10.1.5	Units	#		This is a 1 character alphanumeric field (A1). The analyzer only uses seconds (**s**) as units.
10.1.6	Reference Range	(@)		The following text is used: **nnn s to nnn s** Where nnn is the low and high reference range values entered on the analyzer.

ASTM field[a)]	Field name	Transmitted to host	Received from host	Description
10.1.7	Results Abnormal Flags	(@)		The following code is used: **L** Below low Normal **H** Above high Normal **S** Data Measurement abnormal (see comment record for details) This field can also be null. If an analyzer condition exists that affects the result, a Comment Record will be associated to the Result Record to indicate further information about the Data Measurement.
10.1.9	Result Status	(@)		The following code is used: **F** Final Result (not supported) **R** Result was previously transmitted **S** Partial result (not supported) Otherwise field will be null (or blank).
10.1.11	Operator ID	(@)		This field will contain the logged in User ID when the test was started. (A20)
10.1.13	Date/Time Test Completed	(@)		This field will contain the date and time the result was produced (**YYYYMMDDHHMMSS**).
10.1.14	Instrument ID	(@)		This field will contain the identity of the analyzer which performed the analysis. PFA-200-**nnnnnnnnnn-P** where **nnnnnnnnnn** is the serial number of the analyzer where **P** is the position (**A** or **B**) the cartridge was run on.

Structure of the result record

a) Field numbers not listed in this table are not supported. If transmitted from the host they will be ignored and they will always be null when transmitted from the analyzer.
b) Indicates supported field for identified communication direction.

Example Result record: analyzer to host

R|1|^^^ADP|110|s|80 s to 180 s||||User1||20100727121212|PFA-200

0123456789-A<CR>

7.7 Comment record

ASTM field[a)]	Field name	Transmitted to host	Received from host	Description
11.1.1	Record Type ID	C	Not supported, if transmitted by LIS host it will be ignored	The analyzer transmits upper case characters. Comment records are never accepted from a LIS or host system.
11.1.2	Sequence Number	(@)[b)]		Sequential number starting with 1.

ASTM field[a)]	Field name	Transmitted to host	Received from host	Description
11.1.3	Comment Source	I		The following code is used: **I** Clinical analyzer system
11.1.4	Comment Text	(@)^(@)		This field will have 2 components. The Comment Code followed by Comment Text. See next table for Comment Codes and Comment Text formats.
11.1.5	Comment Type	(@)		The following code is used: **I** analyzer flags

Structure of the comment record

a) Field numbers not listed in this table are not supported. If transmitted from the host they will be ignored and they will always be null when transmitted from the analyzer.
b) Indicates supported field for identified communication direction.

With every result a comment record is sent containing the comment code (even if it is 0). The following Comment Codes are used:

Comment Code	Comment Text	Note
SC101	Invalid Test. No Test Cartridge in A	n.a.
SC102	Invalid Test. No Test Cartridge in B	
SC201	Invalid Test. Invalid Test Code in A	
SC202	Invalid Test. Invalid Test Code in B	
SH100	Invalid Test. Processing Error	
SS210	Invalid Test. Flow Obstruction	
SS230	Invalid Test. Invalid Channel	
SU200	Invalid Test. Test Canceled	
SV210	Invalid Test. Maximum Syringe Travel	
SV220	Invalid Test. Maximum Test Time	
SV300	Invalid Test. Air Leak	
SS211	No Closure. Flow Obstruction	Data Measurement will have a Results Abnormal Flag of A and a secondary GE100 comment.
SS220	No Closure. Sample Depleted	
SV210	No Closure. Maximum Syringe Travel	
SV220	No Closure. Maximum Test Time	
GE100	No Closure. Value greater than or equal to Data Measurement	Data Measurement will have a Results Abnormal Flag of **A**.
R001	{Cartridge lot number}	Comment text contains the cartridge lot number.

Comment codes

Depending on the language settings in the PFA-200 software, the error flags will be transferred in the respective language. For detailed information on errors flags, see the instruction manual of the system.

Example Comment record: analyzer to host

C|1|I|GE100|No Closure. Value greater than or equal to Data Measurement|I<CR>

7.8 Query record (Query)

ASTM field[a)]	Field name	Transmitted to host	Received from host	Description
12.1.1	Record Type	Q	Q	The analyzer transmits upper case characters. Query records are never accepted from a LIS or host system.
12.1.2	Sequence Number	(@)[b)]	(@)	Sequential number starting with 1 and incrementing for each record transmitted.
12.1.3	Starting Range ID	^(@)	^(@)	To request test orders a single Sample ID will be transmitted. This field has 2 components: **Patient ID** (not supported) **Sample ID** (A20) Note: Use of the repeat delimiter is not supported in this field.
10.1.13	Request Information Status Code	O	(@)	Order and demographics request is only request the analyzer will make. **X** Results cannot be done, request canceled. If this is transmitted by LIS host, the analyzer will indicate no test order.

Structure of the query record

a) Field numbers not listed in this table are not supported. If transmitted from the host they will be ignored and they will always be null when transmitted from the analyzer.
b) Indicates supported field for identified communication direction.

Example Query record: analyzer to host

Q|1|^qc001||ALL|||||||O<CR>

If there are jobs for the sample ID requested by the analyzer they are sent to the analyzer by means of a response message for the request. If there are no jobs then the Q-record with Request Information Status Code = X is used to respond.

7.9 Message terminator record

ASTM field	Field name	Transmitted to host	Received from host	Description
13.1.1	Record Type ID	L	L	-

ASTM field	Field name	Transmitted to host	Received from host	Description
13.1.2	-	1	1	-
13.1.3	-	-	-	This field will always be null.

Structure of message terminator record

ExampleMessage terminator record: analyzer to host

L|1<CR>

ExampleMessage terminator record: host to analyzer

L|1<CR>

7.10 Examples

7.10.1 Query

H|\^&|1||PFA-200-IN000950|||||||P|LIS2-A3|20170524083831

Q|1|^qc001||ALL||||||||O

L|1|N

7.10.2 Result

H|\^&|1||INNOVANCE PFA-200|||||||P||20100727121412

P|1||P123456||Last^First^M^^2nd|||||||||||||||||||Location|||||||||

O|1|S123456||^^^ADP&^^^ADP|R|||||N||||W|||||||20100727121412|||F||||||

R|1|^^^ADP|110|s|80 s to 180 s|||F||User1||20100727121212|PFA-200

0123456789

R|2|^^^EPI|120|s|100 s to 195 s|||F||User1||20100727121412|PFA-200-0123456789

L|1|

7.10.3 Result QC

H|\^&|1||INNOVANCE PFA-200|||||||Q||20100727121412

P|1|||||||||||||||||||||||||||||||

O|1|S123456||^^^ADP|R||||||Q||||W|||||||20100727121412|||F||||||

R|1|^^^ADP|110|s|80 s to 180 s|||F||User1||20100727121212|PFA-200-0123456789

C|1||R001|L123456|R

L|1|

7.10.4 Result with flags (example 1)

H|\^&|1||INNOVANCE PFA-200|||||||P||20100727121412

P|1||P123456||Last^First^M^^2nd||||||||||||||||||Location|||||||||

O|1|S123456||^^^ADP&^^^EPI|R||||||N||||W|||||||20100727121412|||F||||||

R|1|^^^ADP|>110|s|80 s to 180 s|||F||User1||20100727121212|PFA-200-0123456789

C|1|I|SS211|No Closure. Flow Obstruction|I

R|2|^^^EPI||s|100 s to 195 s|||F||User1||20100727121412|PFA-200-0123456789

C|1|I|SV300|Invalid Test. Air Leak|I

L|1|

7.10.5 Result with flags (example 2)

H|\^&|1||INNOVANCE PFA-200|||||||P||20100727121412

P|1||P123456||Last^First^M^^2nd||||||||||||||||||Location|||||||||

O|1|S123456||^^^ADP&^^^EPI|R||||||N||||W|||||||20100727121412|||F||||||

R|1|^^^ADP|79|s|80 s to 180 s|L||F||User1||20100727121212|PFA-200-0123456789

R|2|^^^EPI|196|s|100 s to 195 s|H||F||User1||20100727121412|PFA-200-0123456789

L|1|

7.10.6 Result QC with flags

H|\^&|1||INNOVANCE PFA-200|||||||Q||20100727121412

P|1||||||||||||||||||||||||||||||

O|1|S123456||^^^ADP|R||||||Q||||W|||||||20100727121412|||F||||||

R|1|^^^ADP|>110|s|150 s to 180 s|L||F||User1||
20100727121212|PFA-200-0123456789

C|1|I|SS211|No Closure. Flow Obstruction|I

C|2|I|R001|L123456|R

L|1|

7.10.7 Result QC with flags (example 2)

H|\^&|1||PFA-200-IN000950|||||||Q|LIS2-A3|20170524084954

P|1||||^^^|||||||||||||||||||||||||||||

O|1|qc001||^^^|||||||Q||||W|||||||||||||||

R|1|^^^EPI|155|s|115 s 175 s|A||||Service||20170524084628|PFA-200-IN000950-A

C|1|I|^|R

C|2|I|SS220^No Closure. Sample Depleted|I

C|3|I|GE100^No Closure. Value greater than or equal to data measurement|I

R|2|^^^EPI|169|s|115 s 175 s|A||||Service||20170524084946|PFA-200-IN000950-B

C|2|I|^|R

C|3|I|SS220^No Closure. Sample Depleted|I

C|4|I|GE100^No Closure. Value greater than or equal to data measurement|I

L|1|N

8 Revision information

The revision information lists topics that have changed since the previously published version of this document.

Due to a change in layout and a change in the authoring tool, the content and structure of the manual had to be slightly revised compared to the previous version. However, this revision did not result in any significant changes in content.

In addition to the editorial changes, the following new content has been introduced:

- Corrections, for example, of terminology, and improvements due to regulatory input as well as customer and internal feedback.
- The manual has been updated to meet the requirements of the in vitro diagnostic medical devices Regulation (EU) 2017/746.

CE

Siemens Healthineers has validated the provided instructions, reagents, instrument, software and customizable features for this system to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and test results.

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