Revised January 2003 - 2.0_en

14. Technical Information

14.1 Instrument Specifications

Name	Automated Blood Coagulation Analyzer CA-500 Series	
Model	CA-510/CA-520/CA-530/CA-540/CA-550/CA-560	
Analysis parameters/ Calculated parameters	Prothrombin Time (PT)	Analysis: sec. Calculated parameters: PT ratio, INR, Derived Fbg (DFbg)
	Activated Partial Thromboplastin Time (APTT)	Analysis: sec.
	Fibrinogen (Fbg)	Analysis: sec. Calculated parameter: mg/dL
	Thrombin Time (TT)	Analysis: sec.
	Protein C coagulometric (PCcl)	Analysis: sec. Calculated parameters: %
	Batroxobin (BXT)	Analysis: sec.
	Factor Assay (II, V, VII, VIII, IX, X, XI, XII)*	Analysis: sec. Calculated parameters: %
Model	CA-530/CA-540/CA-550/CA-560	
Analysis parameters/ Calculated parameters	Antithrombin III (AT3)	Analysis: ΔOD/min. Calculated parameter: %
	Protein C chromogenic (BCPC)	Analysis: ΔOD/min. Calculated parameters: %
	Heparin (Hep)	Analysis: ΔOD/min. Calculated parameters: IU/mL
Model	CA-550/CA-560	
Analysis parameters/ Calculated parameters	D-Dimer (AdDD)	Analysis: ΔOD Calculated parameters: mg/L (FEU)

(*) Data evaluated for factors VII and VIII only.

Revised August 2003 - 2.0_US

Analysis Principles	Coagulation Reaction Detecting Method (Scattered Light Detection Method)	A mixture of plasma and reagent is exposed to red light (660 nm). Turbidity change occurring when Fibrinogen is transformed to Fibrin is detected as a change in its scattered light, then coagulation time is measured.
	Coagulation Point Detection Method (Percent Detection Method)	Assume that scattered light intensity just after detection commencement is 0%, and the intensity when coagulating reaction has ended is 100%, then the time interval taken until the scattered light set at the coagulation detecting point has been reached is the coagulation time.
	Chromogenic Method* (Colorimetric Method /Rate Method)	Plasma, reagent, and substrate are mixed to start reaction, and change in extinction of pigment in free P-nitroaniline is detected and activity value is calculated.
	Immunology Method**	Sample and Latex reagent are mixed to start reaction, and variation in absorbance of produced Latex clump is detected and calculated.
Simultaneous 5-parameter random Analysis	Random analysis is possible. (5 parameters from PT, APTT, Fbg, TT, PCcl, BXT, Factor Deficiency, AT3, BCPC, Hep and AdDD)	
Detection Time	Coagulation reaction is detected within maximum detection time and coagulation time is measured.	
	Typical maximum detection time	120 sec. for PT 100 sec. for Fbg 190 sec. for others (Coagulation Method) 30 sec. for AT3 180 sec. for D-Dimer
	Maximum detection time that can be set	600 sec. for each parameter
Processing Capability	Maximum: Approx. 54 tests/hr Average (Simultaneous analysis of 3 parameters - PT, APTT, Fbg): Approx. 43 tests/hr Analysis of AT3 parameter: Approx. 18 tests/hr Analysis of AdDD parameter: Approx. 10 tests/hr Average (Simultaneous analysis of 4 parameters - PT, APTT, Fbg, AT3): Approx. 32 tests/hr Average (Simultaneous analysis of 4 parameters - PT, APTT, Fbg, AdDD): Approx. 24 tests/hr	

(*) CA-530, CA-540, CA-550 and CA-560 only.

(**) CA-550 and CA-560 only.

Revised August 2003 - 2.0_US

Analysis Range	Fibrinogen Concentration	The range between 25 mg/dL and 1000 mg/dL can be analyzed. However, over 450 mg/dL is analyzed via dilution in low concentration mode (1:20 dilution). Under 50 mg/dL is analyzed via dilution in high concentration mode (1:5 dilution).
	D-Dimer Concentration	With an applicable reagent (Advanced D-Dimer), the range between 0.43 mg/L (FEU) and 99.99 mg/L (FEU) can be analyzed. However, 17.00 mg/L (FEU) or more is analyzed via dilution in high concentration mode (+AdD, 1:8 dilution).
Plasma Volume Required	Prothrombin Time (PT):	50 µL
	Activated Partial Thromboplastin Time (APTT):	50 µL
	Fibrinogen (Fbg):	10 µL
	PCcl:	5 µL
	Batroxobin (BXT):	50 µL
	Extrinsic Factor Deficiency (II, V, VII, X):	5 µL
	Intrinsic Factor Deficiency (VIII, IX, XI, XII):	5 µL
	Antithrombin III (AT3) (Berichrom Antithrombin III (A)):	10 µL
	Protein C (BCPC):	20 µL
	Heparin (Hep):	20 µL
	D-Dimer (AdDD):	50 µL
Reagents Required	Refer to “5.6 Prepare Reagents”.	

Revised August 2003 - 2.0_US

Manufacturers Reproducibility Data

Reproducibility	Prothrombin Time (PT)	C. V. 2% or less
	Activated Partial Thromboplastin Time (APTT)	C. V. 2% or less
	Fibrinogen (Fbg):	C. V. 5% or less
	Thrombin Time (TT)	C. V. 10% or less
	PCcl	C. V. 5% or less
	Batroxobin (BXT)	C. V. 4% or less
	Extrinsic Factor Deficiency (II, V, VII, X)*	C. V. 5% or less
	Intrinsic Factor Deficiency (VIII, IX, XI, XII)*	C. V. 5% or less
	Antithrombin III (AT3)	C. V. 5% or less
	Protein C (BCPC)	C. V. 5% or less
	Heparin (Hep)	C. V. 5% or less
	The above data are variation coefficients for coagulation time (seconds) and activity percentage (AT3, PC, Hep) when Dade® Ci-Trol® Level I (control plasma) is analyzed 10 times using the reagents below. • Dade® Thromboplastin·C plus • Dade® Actin® • 20 mM, 25mM Calcium Chloride Solution • Owren's Veronal Buffer • Dade® Thrombin Reagent • Batroxobin Reagent • Berichrom° Antithrombin III (A) • Berichrom° Protein C • Berichrom° Heparin	
	D-Dimer The above data is the variation coefficient when a standard solution of D-Dimer (concentration 3.4 - 5.1 mg/L (FEU)) is analyzed 10 times using the reagents below. • Advanced D-Dimer	C. V. 10% or less

(*) Data evaluated for factors VII and VIII only.

Caution

Results should always be evaluated in conjunction with clinical and other laboratory findings.

Independently of the concentration of samples, non-specific reactions may be obtained in some cases and therefore the dilution of samples may lead to discordant results in certain cases.

Revised August 2003 - 2.0_US

Reproducibility Data according to FDA Guidelines

Reproducibility	Prothrombin Time (PT)	C. V. 5 % or less (Unit: Seconds)
	Activated Partial Thromboplastin Time (APTT)	C. V. 3 % or less (Unit: Seconds)
	Fibrinogen (Fbg)	C. V. 5 % or less (Unit: g/L)
	Thrombin Time (TT)	C. V. 7 % or less (Unit: Seconds)
	Protein C clotting (PCcl)	C. V. 6 % or less (Unit: activity-%)
	Batroxobin (BXT)	C. V. 2 % or less (Unit: Seconds)
	Extrinsic Factor Deficiency (VII)*	C. V. 9 % or less (Unit: activity-%)
	Intrinsic Factor Deficiency (VIII)**	C. V. 8 % or less (Unit: activity-%)
	Antithrombin III (AT3)	C. V. 10 % or less (Unit: activity-%)
	Protein C chromogenic (BCPC)	C. V. 4% or less (Unit: activity-%)
	Heparin (Hep)	C. V. 8% or less (Unit: IU/mL)
	Advanced D-Dimer	C. V. 3% or less (Unit: mg/L FEU)
	The above data are variation coefficients for coagulation times in seconds, activities in activity percentage or concentrations in IU/ml or mg/dl (Fbg) taken from 40 analyses of Dade® Behring Control Plasma N, Control Plasma P, Ci-Trol®, pathological plasma pool or normal plasma pool using the reagents below. • Thromborel® S Reagent • Dade® Actin® FSL Activated PTT Reagent • Calcium Chloride Solution (0,025 mol/L) • Owren's Veronal Buffer • Test Thrombin Reagent • Factor Deficient Plasma • Berichrom° Antithrombin III • Protein C Reagent • Berichrom° Protein C Reagent • Berichrom° Heparin Reagent • Dade® Thrombin Reagent • Batroxobin Reagent • Advanced D-Dimer	

(*) Data evaluated for Factor VII only.

(**) Data evaluated for Factor VIII only.

Caution

Results should always be evaluated in conjunction with clinical and other laboratory findings.

Independently of the concentration of samples, non-specific reactions may be obtained in some cases and therefore the dilution of samples may lead to discordant results in certain cases.

Revised August 2003 - 2.0_US

Display and Entry	3.2 in x 4 in liquid crystal display (with black and white LCD backlight) Touch panel type	
Printout	Internal printer prints out analysis data and graphic prints	
External Input/Output	Bit serial voltage signal (RS-232C)	
Cooling of Reagents	The cooling unit performs cooling with the Peltier element*.	
	Reagent holder:	4-positions (15ºC±2ºC, when room temperature is 15 - 35ºC)
Reagent Dispensing	The incubation pipette detects the reagent surface and aspirates/dispenses reagent with the syringe.	
Sample Dispensing	The incubation pipette detects the sample surface, aspirates a sample with the syringe from a tube on the rack, and dispenses it into a reaction tube in the reaction tube rack.	
SAMPLE TUBE	Sample Tube:	60 MAX (30-tube rack x 2)
Detector	Photo Detection Unit:	6 wells (4 wells for coagulation analysis, 1 well for chromogenic analysis*, and 1 well for immunology analysis**) The light-emitting diode for photodetection is ON only during analysis.
	Heater Section:	6-well
Temperature Control	Detector:	37ºC±1.0ºC
	Sample Incubator Section:	37ºC±1.0ºC
	Reagent Pipette:	37ºC±1.0ºC (When room temperature is 15 - 35ºC)
	Cooling Unit*:	15ºC±2ºC
Time Taken to Reach Set Temperature	Within 30 minutes after power supply turn-on (when room temperature is within the temperature range of 15-35ºC)	
STAT Sample Processing	The routine analysis can be interrupted for preferential processing of a specified sample contained in a sample collection tube.	
Number of Stored Samples	Analysis data:	300 samples (a maximum of 1500 tests) (Latest 600 tests only for coagulation curve)
Quality Control	$\overline{X}$ Control (L-J Control):	180 points x 6 files, 14 parameters
Standard Curve	6 points, 14 parameters	
Electrical Rating	Rated Voltage:	117 V AC ± 10%, or 230 V AC ± 15%
	Frequency:	50 Hz or 60 Hz
	Power consumption (Main unit):	380 VA or less (with CA-550) 400 VA or less (with CA-560)
	Heat Compensation Required:	Approx. 1365 BTU/h (344 kcal/h)
Dimensions and Weight	Width (±3%):	Approx. 540 mm
	Depth (±3%):	Approx. 470 mm
	Height (±3%):	Approx. 487 mm
	Weight (±3%):	Approx. 45 kg
	The dimensions exclude the projections.	
Protection Type	Class I Equipment	

Revised September 2003 - 2.0_en

EMC (Electro-magnetic compatibility)	This equipment is in conformity to the following IEC (EN) standard. IEC 61326-1: 97+A1: 98 (EN 61326: 97+A1) Electrical equipment for measurement, control and laboratory use -EMI requirements -EMI (Class B) -EMS (Immunity test requirements for equipment intended for use in industrial locations)

(*) CA-530, CA-540, CA-550 and CA-560 only.

(**) CA-550 and CA-560 only.

Revised January 2003 - 2.0_en

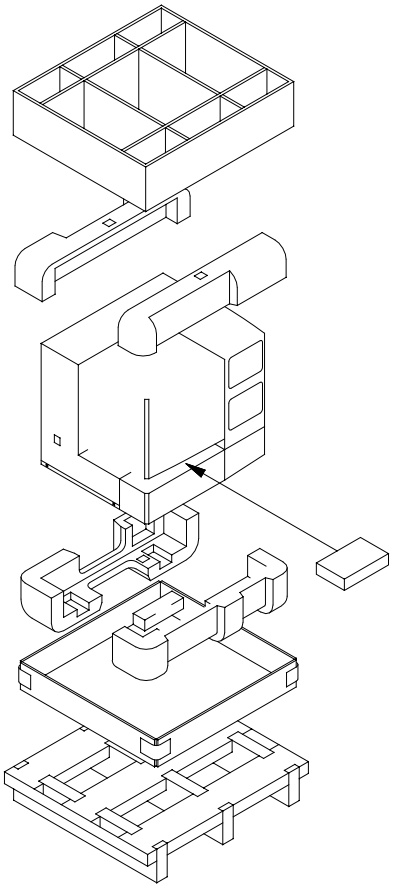
14.2 Installation

Introduction

This product is a clinical test instrument. A Sysmex representative is responsible for unpacking, installing, and initial setup to ensure its proper and safe operation. The next several pages will give some essential information for installation of this instrument.

Check before Installation

Make sure the instrument is free from external flaws and check the quantities of the supplied parts.



Revised January 2003 - 2.0_en

Unpacking Check List

Part No.	Description	Quantity
		117 V
461-2655-0	INSTRUCTION FOR USE CA-500 series	1
266-5106-0	Fuse 250V 6.3A ST4-6.3A-N1 (N.Amer)	2
663-0213-6	Sample Tube Spacer 13 Phi	1
369-5982-2	Indication Mark No.954 (CA-510, CA-520, CA-530 and CA-540 only)	1
369-5088-5	Indication Mark No. 1068 *	1
921-0351-8	Paper Thermal F1-2 (2/Pack)	1
793-0012-1	Power Cord No. 4 (N.Amer)	1
541-1352-1	Push Vial PV-10	2
541-0541-8	Reaction Tube	60
663-0206-0	Reagent Rack Assy	1
663-0209-1	Rinse Bottle Assy (2 L)	1
663-0402-6	Rinse Bottle Assy (5 L) *	1
833-3895-6	Sample Rack No. 3 w/Holder #55	1
663-0208-7	Reaction Tube Rack **	4 (2)
663-0211-9	Trap Chamber Complete	1
663-0207-3	Reaction Tube Trash Box	1
663-0210-5	Waste Bottle Assy (2 L)	1
663-0403-0	Waste Bottle Assy (5 L) *	1
013-1771-4	SLD Vial Assy (10/pack)	1
363-2558-6	Holder No.89	2

(*) CA-550 and CA-560 only.

(**) The number in ( ) is for CA-510, CA-520, CA-530 and CA-540.

Note

If you need to order supplies or replacement parts, please contact your local Sysmex representative.

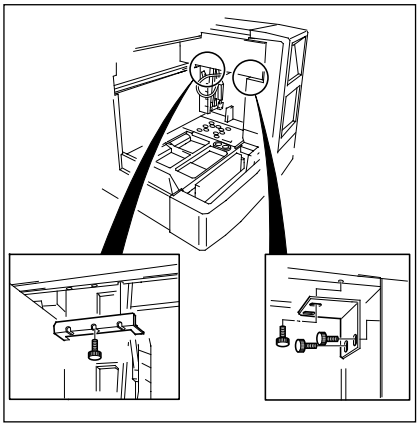
Revised September 2003 - 2.0_US

Installation Space

Refer to “Installation Space” of “4.2 Installation Location”.

Remove Shipping Clamps

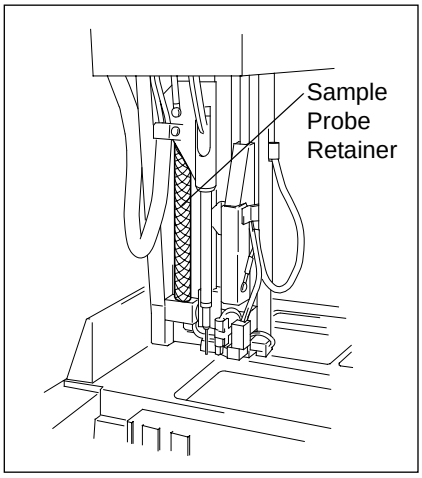
Remove the shipping clamps used on movable components of the instrument.



1. Open the front cover of the main unit.
2. Remove the X-Y mechanism fixing metals.

   Two fixing metals are retained with screws as shown. Loosen the screws and remove the metals.

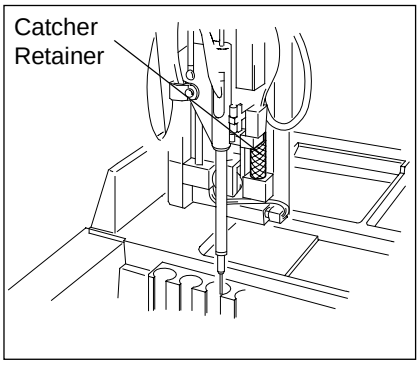
> **Important**
> Unless the fixing metals are removed, the instrument cannot operate.



3. Move the sample probe unit by hand to a place where it is easy to operate.

   Remove the sample probe retainer.

> **Important**
> Unless the retainer is removed, the instrument cannot operate.



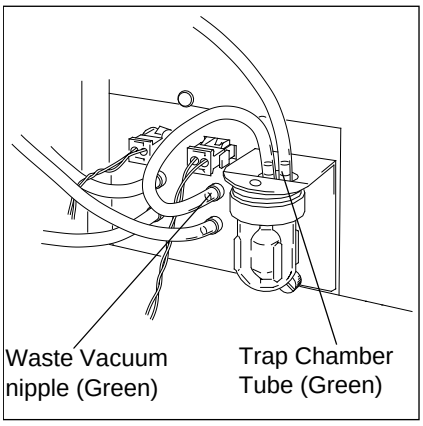
4. Raise the sample probe by hand to a place where it is easy to operate.

   Remove the catcher retainer.

> **Important**
> Unless the retainer is removed, the instrument cannot operate.

Revised January 2003 - 2.0_en

Attach Trap Chamber



1. Attach the supplied trap chamber to the rear panel.

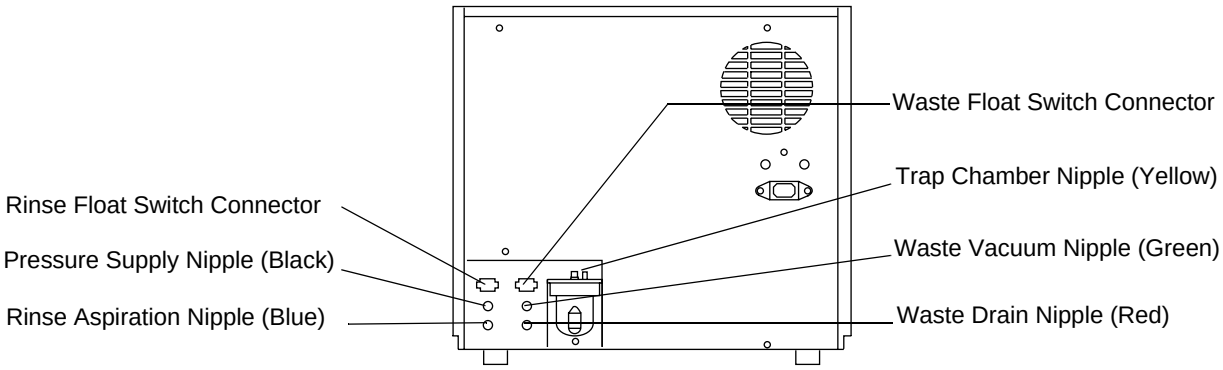
   Connect the trap chamber tube (green) to the waste vacuum nipple (green) on the rear panel.

Risk of Infection

When draining the trap chamber, always wear latex or non latex examination gloves. After completing the operation, be sure to wash hands in anti-septic solution. If hands should be contaminated with blood, there is a hazard of being infected by pathogenic bacteria.

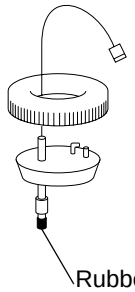
Connect Rinse Bottle and Waste Bottle

Connect the rinse bottle and the waste bottle to the nipples on the instrument rear panel.



1. Connect Rinse Bottle.
   1) Connect the rinse bottle to the pressure supply nipple (black), and rinse aspiration nipple (blue) on the rear panel, at places where the color matches with the bottle.
   2) Connect the level-detecting float switch to the float switch connector on the rear panel.
2. Connect Waste Bottle.
   1) Connect the waste bottle tube (red) to the waste drain nipple (red) on the rear panel. Connect the waste bottle tube (yellow) to the trap chamber nipple (yellow).
   2) Connect the level-detecting float switch to the float switch connector on the rear panel.

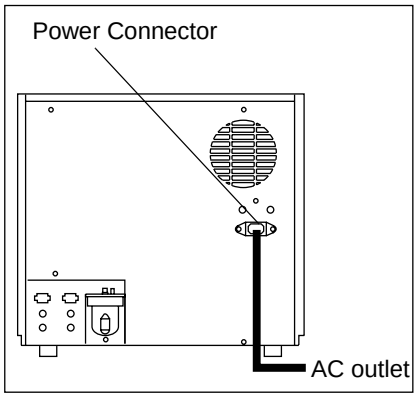
Revised November 2003 - 2.0_en



Important

- Even at a facility equipped with the waste channel (drain system), the waste bottle should be connected. Also, put the rinse bottle and the waste bottle at the same level as the instrument.
  Be sure not to use any other tube than the supplied one; otherwise, the instrument's hydraulic system may fail to operate properly.
- Remove the rubber tube that locks the float switch in the rinse bottle and waste bottle. This rubber tube serve to prevent vibration in transit.

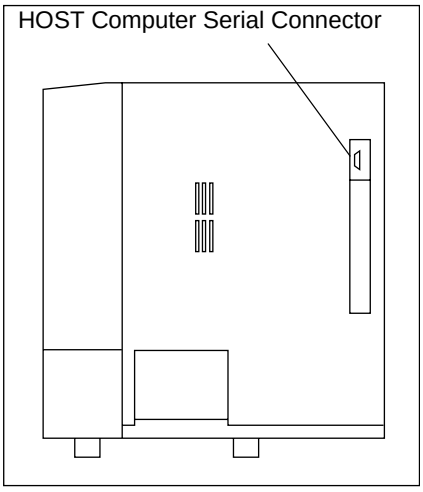
Connect Power Cord and Connection Cord



1. Connect the supplied power cord.
   1) Make sure the power switch is OFF, at “O”.

Caution

Confirm the power switch is OFF, at “O,” before routing the power cord. Make sure to ground the AC outlet; otherwise, there is a hazard of electrical shock.



2. Connect the cable to link with the host computer.
   1) Make sure the power switch is OFF, at “O”.
   2) Connect the connection cord to Host Computer Serial Connector on the right side panel and tighten the screw to fix it.

Important

Confirm the power switch is OFF, at “O”, before routing the connection cord; otherwise, there is a hazard of electrical shock.

Note

- For setting host computer interface parameters, refer to “10.14 Devices to be connected”.
- The connection cord for the host computer is not included in the supply parts.

Revised January 2003 - 2.0_en

Set Print Paper

Refer to “11.8 Supply Printer Paper”.

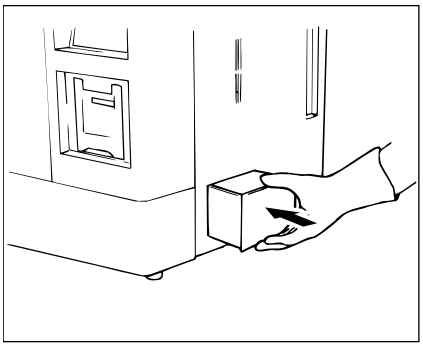
Adjust LCD Contrast

Refer to “ Contrast Adjustment for LCD Screen” of “4.3 Basic Instrument Settings”.

Replenish Rinse Solution

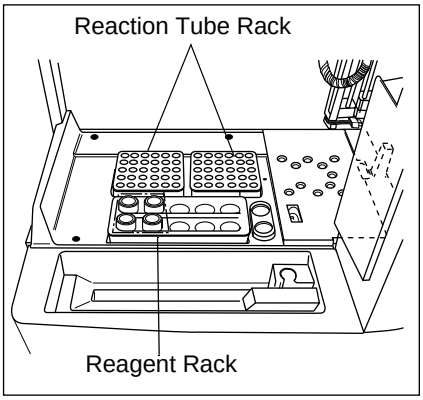
Refer to “11.11 Prime Rinse Solution to Hydraulic Line”.

Set Tube Trash Drawer



Set the supplied tube trash drawer.

Set Reagent Rack and Reaction Tube Rack



Set the supplied reagent rack and reaction tube rack.

Affix Indication Mark No. 954, No. 1068 on the reagent rack.

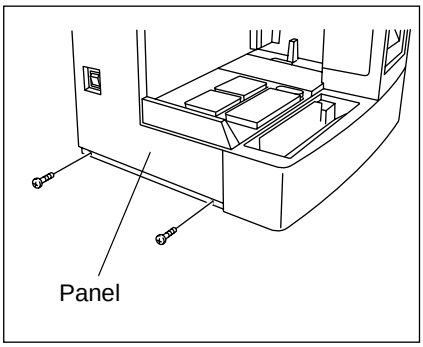
Revised January 2003 - 2.0_en

Install Sampler with ID Barcode Scanner (Option)

An optional Barcode Scanner is installed on the CA-550, as follows.

1. Remove the left side panel of the main unit.

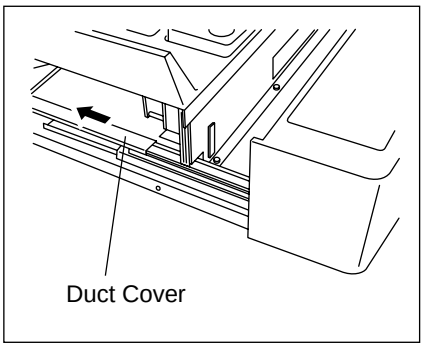
   Loosen the screws as shown to remove the panel.



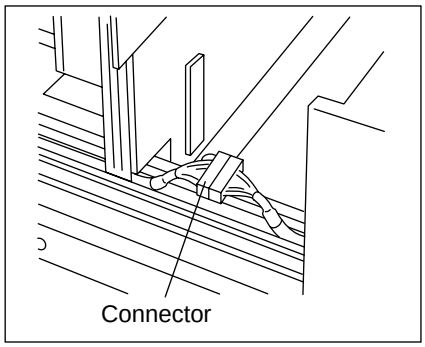
2. Remove the sampler.

   1) Pull the sampler forward.

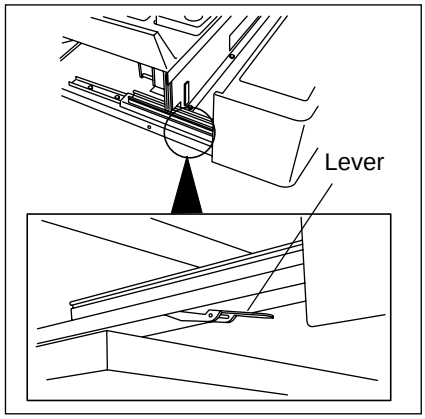
      Pull it out until it stops against the stopper.



   2) Remove the duct cover for the sampler slide rail by sliding it backward.



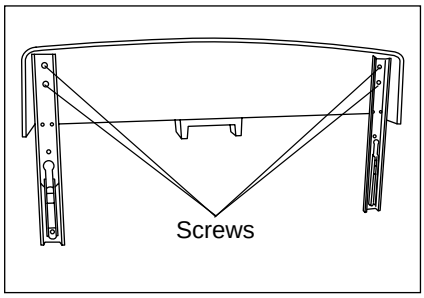
   3) Pull out the connector from the duct, and disconnect the connector.



   4) Remove the sampler.

      Release the stoppers by pushing the stopper levers with your fingers, and remove the sampler.

Revised January 2003 - 2.0_en



3. Attach the slide rail to the sampler with the ID barcode scanner.

   1) Remove the slide rail from the removed sampler.

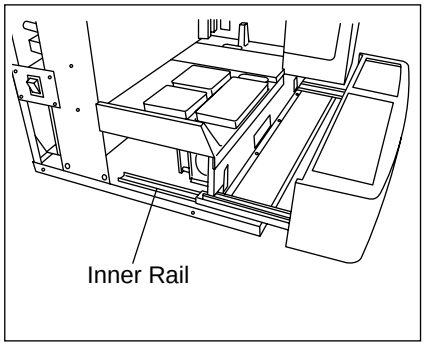
      Loosen the screws as shown and remove the slide rail from the sampler.

      Take care not to lose the slide rail, screws, or washers that were removed, as they must be attached to the sampler with the ID barcode scanner.

   2) Attach the slide rail to the sampler with the ID barcode scanner.

      Mount the duct-attached slide rail to the sampler onto the side where the cable protrudes. All four screws should be temporarily tightened.

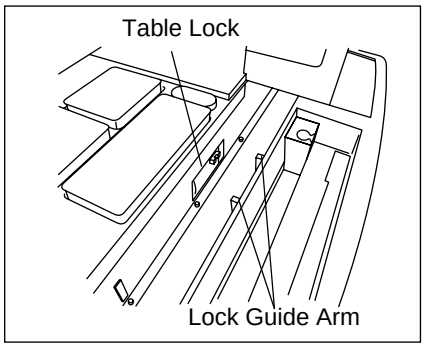
   3) Insert the cable from the sampler into the slide rail duct.



4. Install the sampler with the ID barcode scanner to the main unit.

   1) While finger-pushing the stopper lever to release the stopper, push in the sampler a few centimeters on the inner rails of the main unit.

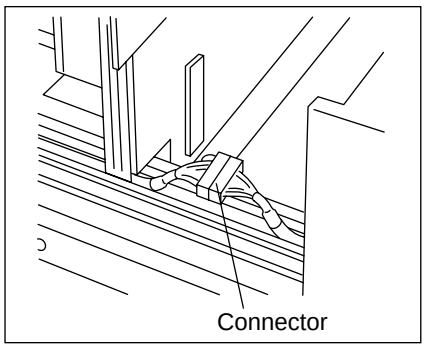
> **Important**
> Do not let go with your hands until you are sure the sampler with ID barcode scanner will not disconnect.



   2)Push the sampler with ID barcode scanner in parallel.

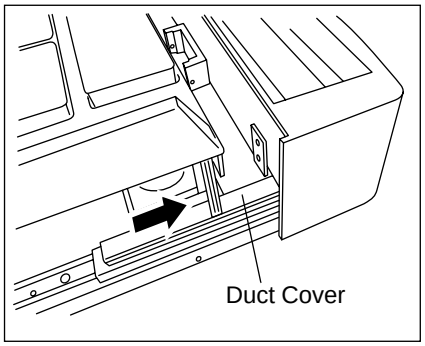
   Push it in until the lock guide arms fit in the table lock of the main unit. As you push it, the sampler will feel heavier, but keep pushing little by little.

> **Important**
> The table lock is only 1 mm apart from the lock guide arms. In pushing, take care not to allow the lock guide arm to contact the under panel.



   3) Connect the connector and put it in the duct.

Revised January 2003 - 2.0_en



4) Attach the duct cover.

The duct cover should be attached so that it will cover the outlet for the cable of the sampler with ID barcode scanner.

5) Repeat pushing in and pulling out the sampler with ID barcode scanner several times.

6) With the sampler pulled out in parallel, fully tighten the screws that were temporarily tightened before.

7) Make sure that the sampler with ID barcode scanner will slide in and out smoothly.

5. Attach the left side panel of the main unit.
6. The instrument is ready to be set up by your local service representative.

Revised January 2003 - 2.0_en

14.3 Serial Interface for Host Computer

A serial interface is available on the Main Unit rear panel for connecting to a host computer. The bit serial voltage type, which conforms to the RS-232C interface, is used for input and output to and from this instrument.

Connection

Connect an EIA RS-232C V.24 standard 9-pin D-SUB, female (body = female and pins = male) connector (DB-9S) to the serial interface on the Main Unit rear panel. Fixing screws for this connector have a thread which is measured in needs.

Input/Output Signals

Pin	Signal Name	Flow Direction
1		
2	Receive Data (RxD)	IN (From Host to CA)
3	Transmit Data (TxD)	OUT (To Host from CA)
4	Data Terminal Ready (DTR)	OUT (To Host from CA)
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	IN (From Host to CA)
7	Request to Send (RTS)	OUT (To Host from CA)
8	Clear to Send (CTS)	IN (From Host to CA)
9		

Communication Format

Asynchronous Half Duplex Mode

Communication Settings

Setting program “Settings” - “I/O Setting” - “Host Computer” has to be executed to set the interface parameters. Underlined items are selected as the initial configuration. Refer to “10.14 Devices to be connected”.

Items	Selections
Status	Connected Not Connected
Baud Rate (BPS)	600 1200 2400 4800 9600
Character Length	7-Bit 8-Bit
Stop Bit	1-Bit 2-Bit
Parity	None Even Odd
Class	Class A Class B
Interval (second)	0 2 3 5 7 10 15
Inquiry	Auto Manual

Revised January 2003 - 2.0_en

Items	Selections
Format	CA1000 CA500 ASTM
ACK Text	STX-ACK-ETX ACK/NAK

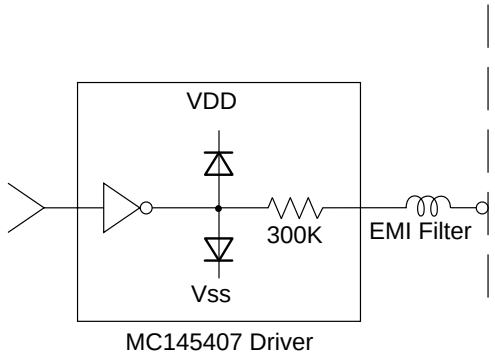
Signal Level

Signal level of the RS-232C conforms to the EIA RS-232C V.24 standard.

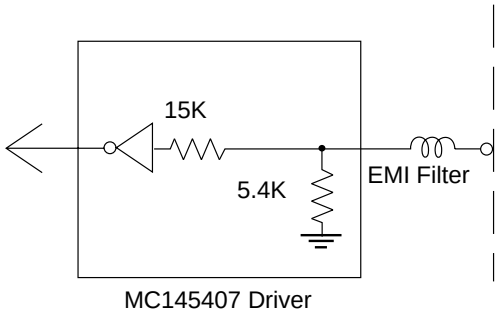
Level	Binary State	Function
+3 V or Higher	Logic “0”, Start Bit	ON
-3 V or Lower	Logic “1”, Stop Bit	OFF

Interface Circuit

Output Circuit



Input Circuit



Software

1. Code

ASCII codes are used in this interface.

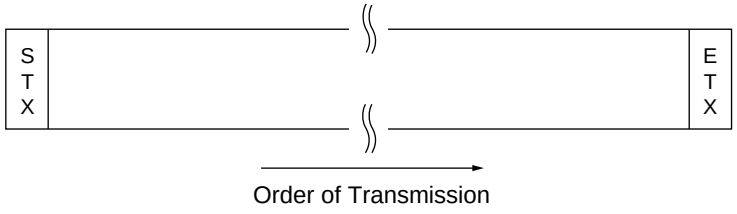
Revised January 2003 - 2.0_en

2. General Function

Function	Description
Analysis data output	Auto Out -- This instrument automatically sends out analysis data after each analysis has been completed.
	Stored Data (batch output) -- This instrument sends out data from the stored data in a batch.
Inquiry (output) and settings from host computer (input)	When this instrument makes an inquiry about order information for the Rack No. and Tube Position No., the host computer gives order information and the sample ID number for each sample in the rack to the instrument.
	According to ID No. read by the optional barcode reader, the host computer gives order information for each sample.

3. Framing of Text

STX (02 in hexadecimal code) is sent prior to data and ETX (03 in hexadecimal code) is sent following data. The text length is within 255 bytes.



4. Communication Protocol

The following 2 protocols are provided in the system. The factory configuration is Class A. Refer to “10.14 Devices to be connected” for setting information.

Class	Description
Class A	One-way transmission to the host computer without requiring ACK (06 in hexadecimal) nor NAK (15 in hexadecimal) from host computer.
Class B	This instrument transmits data and then waits for ACK or NAK to complete the data transmission, which is more secure transmission protocol.

Revised January 2003 - 2.0_en

5. Text Format

The following 3 kinds of formats are provided in the system.

Text Format	Contents of Text
Analysis data format (output)	Output analysis data. When Auto Out is selected or when serial output of stored data is performed, analysis data will be output.
Inquiry text for ID No. and parameter(s) settings	This instrument asks host computer about parameter(s) or about both ID No. and parameter(s).
Settings text for ID No. and parameter(s)	Host computer responds to this instrument the analysis parameter(s) or both ID No. and analysis parameter(s).

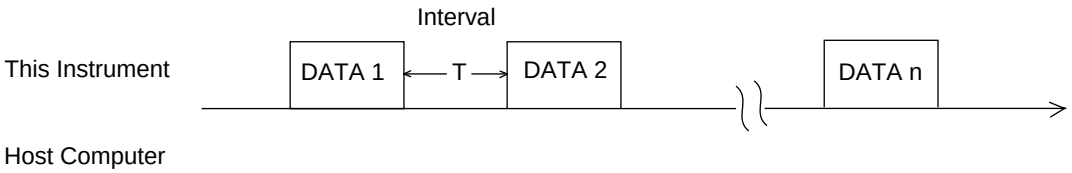
Class A

Data is transmitted in the form of a text or blocks. The host computer checks the start and end characters as well as the parity bit received after each character, but does not transmit any response. Therefore, the instrument will not wait for the response ACK (06 in hexadecimal) or NAK (15 in hexadecimal) from the host computer and transmits data to the host computer in one direction with two control signals (CTS and DSR) only.

This instrument transmits the following data without requiring data from the host computer in Class A mode.

- Auto output of analysis data - Real-time output
- Output of stored data - Batch output

Data will be transmitted by the interval time set in the serial interface settings.



Class B

This class is identical to Class A except for the receiving side. When the host computer receives transmitted data, the host computer transmits a response followed by a sequence. If necessary the host computer also checks the contents of the text (or block). This instrument waits for the response ACK or NAK from the host computer in addition to two control signals (CTS and DSR) and transmits the next sample data upon receiving ACK from the host computer.

Revised January 2003 - 2.0_en

The instrument transmits the following data in Class B mode.

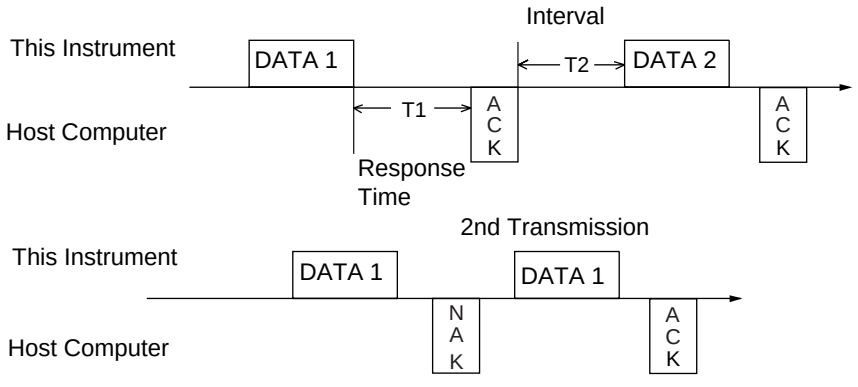
Function	Description
Analysis data output	Auto Out -- This instrument automatically sends out analysis data after each analysis has been completed.
	Stored Data (batch output) -- This instrument sends out data from the stored data in a batch.
Inquiry (output) and settings from host computer (input)	When this instrument makes an inquiry about order information for the Rack No. and Tube Position No., the host computer gives order information and the sample ID number for each sample in the rack to the instrument. Inquiry is made when the **[HC]** key is pressed in the Work List program.
	According to ID No. read by the optional barcode reader, the host computer gives order information for each sample.

Analysis Data Output from This Instrument to Host Computer

This instrument transmits analysis data text to the host computer in the following sequence.

1. This instrument transmits analysis data text to the host computer.
2. The host computer sends ACK (06 H) when the data is received correctly, and sends NAK (15 H) if a communication error occurs.
3. If the reply is ACK, the instrument will complete communication. If the reply is NAK, the instrument will send the same text again (retrying up to 3 times).
4. If the reply is still NAK after sending the same text the third time, the instrument terminates the communication.

> **Note**
> "STX-ACK-ETX" and "STX-NAK-ETX" can be selected instead of ACK and NAK. Refer to "10.14 Devices to be connected" for procedures.



Analysis Order Inquiry to Host Computer

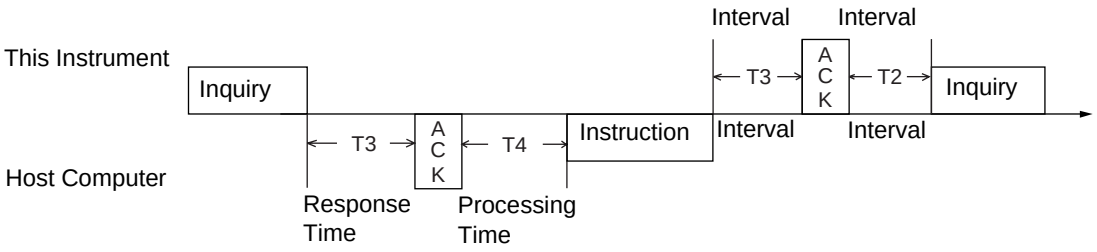
Transmission Protocol should be fixed in Class B to make inquiries regarding order information to the host computer. Selecting Class A will lead to an incorrect communication without showing an error message.

The instrument inquires the order information and receives order information text from the host computer in the following sequence.

1. The instrument sends order inquiry text to the host computer.
2. The host computer verifies the received data and responds by sending NAK (15H) when an error exists. When no error exists, host computer sends ACK (06H) and the order information text that was requested.
3. If the instrument receives NAK from the host computer, the instrument re-sends the inquiry text (retrying up to 3 times). If the instrument receives NAK after 3 retries, the instrument terminates the communication.

   If the instrument receives ACK, the instrument verifies the order information text and sends NAK when an error exists. When no error exists, the instrument sends ACK to the host computer.
4. If the host computer receives ACK from the instrument, the host computer completes the communication of order information for one sample.

   If NAK is received from the instrument, the host computer re-sends the order information text to the instrument (retrying up to 3 times).



Time Interval

The time interval between two data transmissions to the host computer can be selected with the setting program. The interval time means the period after this instrument received the response of ACK/NAK from the host computer until the instrument starts transmission of the next data in Class B mode.

The instrument sends text after the “T2” interval. The interval time can be set in the serial interface settings at 0, 2, 3, 5, 7, 10 or 15 seconds.

Revised January 2003 - 2.0_en

Time-Out Setting

When response time “T1” (shown in Figure C-5) or “T3” or processing time “T4” exceeds the time-out setting, the instrument will terminate the communication. Time-out settings is fixed to 15 seconds.

> Note
> Processing time “T4” is the time that is required for the host computer to process setting text.

Processing Time

For communication without the use of a control wire, response time “T1” or “T3”, and processing time “T4” must be set to an interval of 0.2 seconds or longer. Contact your local service representative for assistance.

If there is no order setting for parameter(s)

When a parameter is not analyzed, enter “000” for the parameter as the setting code.

When there is no analysis parameter order set in the host computer, enter “999” as the setting code. When the instrument receives “999”, the instrument terminates inquiry about analysis parameters of the samples in that rack, and no sample will be analyzed.

Transmission Errors

If this instrument detects an error after transmitting data, an error message will be displayed and transmission of data will be terminated. The customer has to resolve the following error status to transmit data again.

Error Message	Description
Off Line	DSR is OFF.
HC CTS Time Out	CTS does not become ON within 5 seconds after entering a command to transmit data to host computer (RTS turns ON).
HC Communication Error	Parity Error, Overrun Error or Frame Error occurs.
HC ACK Code Error	Host computer does not send a correct response code to this instrument.
HC ACK Time Out	Host computer does not send the response ACK nor NAK to this instrument within 15 seconds after transmitting data.
HC Reception Count Error	This instrument receives NAK after three retries, or failed to receive data four times (transmits NAK 4 times).
HC STX Time Out	After receiving ACK, this instrument does not receive setting text within 15 seconds.
HC ETX Time Out	After receiving STX, this instrument can not receive ETX of setting text within 15 seconds.
Instruction Not Found in Host Computer	In response to analysis parameter of rack position #1, host computer sends “999” as the analysis parameter setting text.

Revised January 2003 - 2.0_en

14.4 Text Format

The instrument transmits (1) Analysis Data, (2) Inquiry Data, and (3) Order Information Data.

This data is distinguished by the Text Distinction Code I. Text Distinction Code I is “D” for the Patient Sample Data, “R” for the Inquiry Data, or “S” for the Order Information Data.

Analysis Data Format

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	“D”
Text Distinction Code II	1	“1” or “2”
Text Distinction Code III	2	“21”
Block Number	2	“01”
Total Number of Blocks	2	“01”
Sample Distinction Code	1	“U”, “E”, “S” or “C”
Date	6	“010131” (yy/mm/dd, mm/dd/yy or dd/mm/yy)
Time	4	1325 (hh:mm in 24-hour clock)
Rack Number	4	“0001” (0001-9999)
Tube Position Number	2	“01” (01-10)
Sample ID Number	15 (or 13)	“123-4567-8901”
ID Information	1	“M”, “A”, “B” or “C”
Patient Name	11	“xxxxxxxxxxx” Spaces (20H), or characters except for the control codes.
Data 1	9	
Data 2	9	
• • •	• • •	
Data n	9	
ETX	1	(03 H)

(a) Text Length = 54 + (9 × n) bytes

The text length varies depending on the number of parameters.

Analysis data should not exceed 255 characters. If it exceeds 255 characters, the analysis data will be divided into blocks.

(b) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.

Revised January 2003 - 2.0_en

(c) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.

(d) Text Distinction Code I is “D” for the analysis data.

Text Distinction Code II is type of analysis data:

“1”: Normal single analysis data

“2”: Mean data of replication analyses.

Text Distinction Code III is always “21”.

(e) Block number and total number of blocks are both usually “01”.

The block number is the serial number of divided blocks.

The total number of blocks is the number of total blocks divided.

(f) Sample Distinction Code

Symbol	Type of Data:
U	Routine analysis data
E	STAT analysis data
C	Quality control analysis data
(space, 20H)	Type of sample is unknown.

(g) Date and time is the time when the analysis data was obtained. Date format conforms the format set in the setting program. Zero suppression is not performed.

(h) Time is expressed in 24-hour clock system. Zero suppression is not performed.

(i) Rack No. indicates the 4-digit Rack No. assigned to each rack which is “0001” through “0099”. STAT samples are assigned a sequential number by the system. Zero suppression is not performed.

> Note
> A sequential number is the number counted up by one each time after turning ON the power.

(j) Tube Position No. is the position number in which the sample was placed within a rack. “01” through “10” can be set when the sample was set in a sample rack. “00” is output for the STAT sample. Zero suppression is not performed.

(k) Sample ID number consists of 15 digits including hyphens “-” (2D in hexadecimal code). Zero suppression is not performed. When No. of digits for the ID number is set in the Settings, Output/Input, HC program, the most significant digit(s) are not output computer if it is set lower than 15 digits.

(l) ID information indicates how the sample ID number was entered or read.

Symbol	Description
M	The sample ID number was entered manually.
A	The sequential number was applied to the sample ID number automatically.
B	The sample ID number was read by the barcode reader.
C	The sample ID number was downloaded from the host computer.

(m) Reserved (Eleven spaces (20H) are set.)

Revised January 2003 - 2.0_en

(n) Data n

Parameter	No. of Characters	Example
Parameter Code	3	Refer to Table “Parameter Code”.
Data	5	Refer to Table “Data”.
Flag	1	“_”, “+”, “-”, “!”, “*”, “<” or “>”. Refer to Table “Flag”.

- Parameter Code

Parameter Code	Parameter	Parameter Code	Parameter
04X	PT	22X	XII
05X	APTT	25X	PCcl
06X	Fbg	26X	BXT
		30X	AT3
12X	II	33X	PC Chrom
15X	V	34X	Hep
17X	VII	50X	+Fbg
18X	VIII	51X	TT
19X	IX	52X	-Fbg
20X	X	61X	AdDD
21X	XI	70X	+AdD

Where, X is:
1: Time
2: Activity percent/concentration
3: Ratio
4: INR
5: dFbg

Note

Additional parameter codes may be added in the future.
The host computer may receive a parameter code not mentioned above; therefore, prepare a host computer program that will ignore such data of a parameter code.

Revised August 2003 - 2.0_US

- Data

  Data is sent without a decimal point.

Data	Units	Output Format Actual data → Data format
Coagulation time	sec, s	XXXX.X → XXXXX
Activity %	%	XXX.X → OXXXX
	No unit	X.XXX → OXXXX
PT ratio, INR		XX.XX → OXXXX
Fbg concentration	mg/dL	OXXX.X → OXXXX
	g/L	OX.XXX → OXXXX
D-Dimer concentration	mg/L (FEU)	XX.XX → OXXXX

Caution

If your host computer receives PT ratio and INR with form of X.XX, contact your local service representative.

Note

- X stands for a figure, O stands for a blank space (20 H).
- When the coagulation time could not be obtained because of an analysis error, an asterisk (*) appears instead of “X” as the coagulation time. If there is an analysis error of mean data, a slash (/) appears in stead of “X”.
- In case of no standard curve, illegal data, or if no coagulation occurs, an appropriate number of hyphens “-” appear instead of “X”. Also if an analysis error occurs due to a hardware problem, spaces (20 H) appear instead of “X”.

- Flag

  A flag indicates whether or not an error occurred during analysis.

Flag	Meaning
space	No error
+	Over the Upper Patient Limit
-	Under the Lower Patient Limit
*	Error occurred during analysis, Fbg data exceeds the analysis range, or replicate difference is too big.
!	Coagulation time was obtained by re-dilution.
>	Over the Upper Report Limit
<	Under the Lower Report Limit

Revised September 2003 - 2.0_US

> **Note**
> The priority order of each flags is (*), (<) or (>), (+) or (-), (!) a space " " in that order.

Inquiry Data Format

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	"R"
Text Distinction Code II	1	"1" or "2"
Text Distinction Code III	2	"21"
Block Number	2	"01"
Total Number of Blocks	2	"01"
Sample Distinction Code	1	A space (20H)
Date	6	"010131" (yy/mm/dd, mm/dd/yy or dd/mm/yy)
Time	4	1325 (hh:mm in 24-hour clock)
Rack Number	4	"0001" (0001-9999)
Tube Position Number	2	"01" (01-10)
Sample ID Number	15 (or 13)	"123-4567-8901"
ID Information	1	"M", "A", "B", "C" or a space " "
(Reserved)	11	"xxxxxxxxxxx"; Eleven Spaces (20H), or characters except for the control codes.
Analysis parameter 1	9	
Analysis parameter 2	9	
• • •	• • •	
Analysis parameter n	9	
ETX	1	(03 H)

(a) Text Length = 54 + (9 × n) bytes

The text length varies depending on the number of parameters.

Inquiry data should not exceed 255 characters. If it exceeds 255 characters, the inquiry data will be divided into blocks.

(b) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.

Revised September 2003 - 2.0_en

(c) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.

(d) Text Distinction Code I is “R” for the inquiry data.

Text Distinction Code II is type of inquiry:

“1”: The key word is “Rack No. and Tube Post.”

“2”: The key word is “Sample ID No.”

Text Distinction Code III is always “21”.

(e) Block number and total number of blocks are both usually “01”.

The block number is the serial number of divided blocks.

The total number of blocks is the number of total blocks divided.

(f) A space (20H) is sent for the Sample Distinction Code.

(g) Date and Time when the inquiry is made. Date is transmitted in the form set by the Setting program. Time is expressed in 24-hour clock system. Zero suppression is not performed.

(h) Rack No. indicates the Rack No. for which the inquiry is made.

“0001” through “0099” can be set. Zero suppression is not performed.

(i) Tube Position No. is the position number in which the sample was placed within a rack. “01” through “10” can be set. “00” is output for the STAT sample. Zero suppression is not performed.

(j) Sample ID number indicates the sample ID number for which the inquiry is made. Sample ID number consists of 15 digits including hyphens “-” (2D in hexadecimal code). When the ID number of 13 digits or less is set, the set ID number is placed in the least significant digits and space(s) (20 H) are padded to the most significant digits to fill up 15 digits.

When inquiry is made by the Rack No., sample ID number will be filled with spaces.

Note

When the barcode label could not be read due to an error or no label is attached on the sample tube, the sample ID No. will become “ERR0000000001”.

(k) ID information indicates how the sample ID number was entered or read.

Symbol	Description
M	The sample ID number was entered manually.
A	The sequential number was applied to the sample ID number automatically.
B	The sample ID number was read by the barcode reader.
C	The sample ID number was set by the host computer.
(space)	The sample ID number was inquired from the host computer with the Rack No.

(l) Reserved and 11 spaces (20H) are filled.

Revised September 2003 - 2.0_en

(m) Data n

Parameter	No. of Characters	Example
Parameter Code	3	Refer to Table “Parameter Code”.
(Reserved)	6	All spaces (20H).

- Parameter Code

Parameter Code	Parameter	Parameter Code	Parameter
040	PT	220	XII
050	APTT	250	PCcl
060	Fbg	260	BXT
		300	AT3
120	II	330	PC Chrom
150	V	340	Hep
170	VII	500	+Fbg
180	VIII	510	TT
190	IX	520	-Fbg
200	X	610	AdDD
210	XI	700	+AdD

Note

Additional parameter codes may be added in the future.
The host computer may receive a parameter code not mentioned above; therefore, prepare a host computer program that will ignore such data of a parameter code.

- Reserved

  All characters are spaces (20H).

Revised August 2003 - 2.0_US

Order Information Data Format

Parameter	No. of Characters	Example
STX	1	(02 H)
Text Distinction Code I	1	“S”
Text Distinction Code II	1	“1” or “2”
Text Distinction Code III	2	“21”
Block Number	2	“01”
Total Number of Blocks	2	“01”
Sample Distinction Code	1	“U”, “E” or “C”
Date	6	“010131” (yy/mm/dd, mm/dd/yy or dd/mm/yy)
Time	4	1325 (hh:mm in 24-hour clock)
Rack Number	4	“0001” (0001-9999)
Tube Position Number	2	“01” (01-10)
Sample ID Number	15 (or 13)	“123-4567-8901”
ID Information	1	“A”, “B” or “C”
Patient Name	11	“xxxxxxxxxxx” Spaces (20H), or characters except for the control codes.
Analysis parameter 1	9	
Analysis parameter 2	9	
• • •	• • •	
Analysis parameter n	9	
ETX	1	(03 H)

(a) Text Length = $(54+9 \times n)$ bytes

The text length varies depending on the number of parameter.

Order information data should not exceed 255 characters. If it exceeds 255 characters, the order information data will be divided into blocks.

(b) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.

(c) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.

(d) Text Distinction Code I is “S” for the order information data.

Text Distinction Code II is type of inquiry:

“1”: The key word is “Rack No. and Tube Pos.”

“2”: The key word is “Sample ID No.”

Text Distinction Code III is “21”.

(e) Block number and total number of blocks are both usually “01”.

The block number is the serial number of divided blocks.

The total number of blocks is the number of total blocks divided.

(f) Sample Distinction Code

Symbol	Type of Data:
U	Routine analysis data
E	STAT analysis data
C	Quality control analysis data

(g) Date and Time when the host computer ordered to the instrument. Date should be transmitted in the form set by the Setting program in the instrument. Time should be expressed in 24-hour clock system. Zero suppression is not performed.

(h) Rack No. indicates the Rack No. into which the sample test tube is placed.

“0001” through “0099” can be set. It is suggested that the STAT sample is assigned a sequential number to distinguish from other STAT samples.

(i) Tube Position No. is the position number in which the sample is placed within a rack. “01” through “10” can be set. “00” should be assigned for the STAT sample.

(j) Sample ID number consists of 15 digits including hyphens “-” (2D in hexadecimal code). When the ID number of 13 digits or less is set, the set ID number is placed in the least significant digits and space(s) (20 H) are padded to the most significant digits to fill up 15 digits.

When the sample is the Quality Control material, assign the QC file number as

“QC01_ _ _ _ _ _ _ _ _ _ _” through “QC06_ _ _ _ _ _ _ _ _ _ _” in which the obtained QC data are to be stored. (“_” represents a space.)

(k) ID information indicates how the sample ID number was entered or read.

Symbol	Description
C	The sample ID number was downloaded from the host computer.
A	The sequential number was applied to the sample ID number automatically.
B	The sample ID number was read by the barcode reader.
M	The sample ID number was entered manually.

(l) Reserved; 11 spaces (20H).

(m) Data n

Parameter	No. of Characters	Example
Parameter Code	3	Refer to Table “Parameter Code”.
(Reserved)	6	All spaces (20H).

Revised September 2003 - 2.0_en

- Parameter Code

Parameter Code	Parameter	Parameter Code	Parameter
040	PT	260	BXT
050	APTT	300	AT3
060	Fbg	330	PC Chrom
		340	Hep
120	II	500	+Fbg
150	V	510	TT
170	VII	520	-Fbg
180	VIII	610	AdDD
190	IX	700	+AdD
200	X	000	Not Analyzed
210	XI	999	Stop order inquiry for the following samples in the racks.
220	XII		
250	PCcl		

Note

Additional parameter codes may be added in the future.
The host computer may receive a parameter code not mentioned above; therefore, prepare a host computer program that will ignore such data of a parameter code.

(n) When no instruction found in host computer:

- If there is no setting parameter in response to the inquiry from the instrument for the ID number, host computer is requested to send “000” as the parameter code.
- If there is no setting parameter in response to the inquiry from the instrument for the Rack number, host computer is requested to send “999” as the parameter code. If the instrument receives “999”, it stops inquiring about following samples that are in the same sample rack.

14.5 ID Barcode

Applicable Barcodes

The types of barcodes acceptable to the instrument and the relation of the check-digit to each barcode type are as follows:

> **Warning**
> Use the check-digit as much as possible. If the check-digit cannot be used, the potential of incorrect reading of the barcode label may be increased.

1. Sample ID No.

Type of Barcode	Check-Digit	No. of Digits for Sample ID No.	No. of Digits for Check-Digit
NW-7 (CODABAR)*	Not Used	1 - 15 digits	Not Applied
	Modulus 11	1 - 15 digits	1 digit
	W. Modulus 11	1 - 15 digits	1 digit
	Modulus 10	1 - 15 digits	1 digit
CODE-39	Not Used	1 - 15 digits	Not Applied
	Modulus 43	1 - 15 digits	1 digit
CODE-128	Modulus 103	1 - 15 digits	1 digit
ITF (Interleaved 2 of 5)	Not Used	1 - 15 digits	Not Applied
	Modulus 10	1 - 15 digits	1 digit
JAN-8	Modulus 10	7 digits	1 digit
JAN-13	Modulus 10	12 digits	1 digit

*: Start and Stop code can be any one of the characters “A”, “B”, “C”, “a”, “b” and “c”.

> Note
> When “C” or “c” is used, make sure that the number should not be the same as the number of QC File No.

2. QC File No.

   QC File No. can be read if printed with NW-7, CODE-39 or CODE-128.

Type of Barcode	Check-Digit	No. of Digits (File No.)	No. of Digits for Check-Digit
NW-7 (CODABAR) *1	Not Used	4 to 13 digits *2	Not Applied
CODE-39 CODE-128	Either of “Use” or “Not Use”	4 digits “QC01”, “QC02”, ... “QC12”	Not Used or 1 digit

*1: Start and Stop code can be any one of the characters “C” and “c”.

*2: Possible applicable number is one of 1 through 9, and must be filled with the same number in all digits.

Revised January 2003 - 2.0_en

Dimensions of Elements

Barcodes consists of five elements: a narrow bar, a narrow space, a wide bar, a wide space, and a gap between characters. Each element has to comply with all of these equations:

(a) Narrow element ≥ 150 µm

(b) Wide element ≤ 1.2 mm

(c) Narrow element ≤ Gap between characters ≤ Wide element

> Note
> ITF does not require above mentioned item (c), since ITF does not use a gap between characters.

Requirements on Wide/Narrow Ratio

For each character, the ratio of the wide element and the narrow element has to comply with all the equations listed below:

(1) $$\frac{\text{Narrow(Max)}}{\text{Narrow(Min)}} \leq 1.3$$

(2) $$\frac{\text{Wide(Min)}}{\text{Narrow(Max)}} \geq 2.2$$

(3) $$\frac{\text{Wide(Max)}}{\text{Wide(Min)}} \leq 1.4$$

Here, the Narrow (Max) means the widest element of narrow elements in a character. The Narrow (Min) means the narrowest element of narrow elements in a character. The Wide (Min) means the narrowest element of the wide elements in a character and the Wide (Max) means the widest element of wide elements in a character.

Optical Requirements

1. Requirement on the Print Contrast Signal (PCS) is:

$$PCS = \frac{Rs - Rb}{Rs} \geq 0.45$$

Rs: the reflectivity of the space (background)

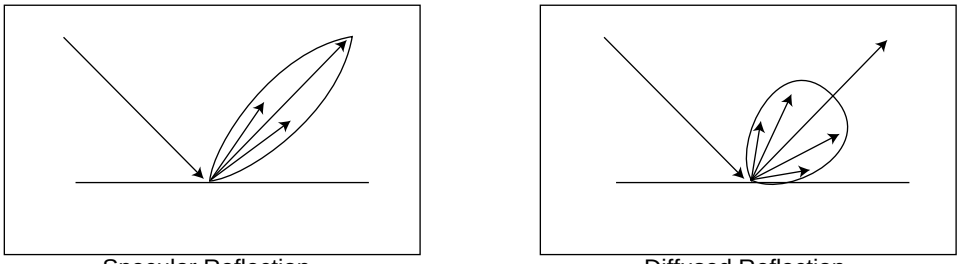
Rb: the reflectivity of the black inked bar

The measuring method conforms to *the JIS (Japanese Industrial Standards) B9550, "5.3 Optical Characteristics of Barcode Symbols"*.

2. Reflective characteristics of the label surface

The barcode reader defines the white and black by the reflected light intensity when the light is applied to the label at an angle of approximately 25°. Therefore, most of the reflection of the label surface should be diffused reflection. For example, a laminated label may cause specular reflection, which will increase the reflection directivity too much and cause the ID reader to miss scan lines. See the following figures.

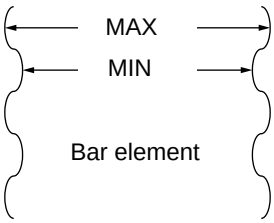
Revised January 2003 - 2.0_en



3. Irregularity and roughness of the printing

When a bar element is magnified, the following may be observed. The variation coefficient (S) in the width of a bar should be less than or equal to 20%.

$$S(\%) = \frac{\text{Max-Min}}{\text{Max}} \times 100$$

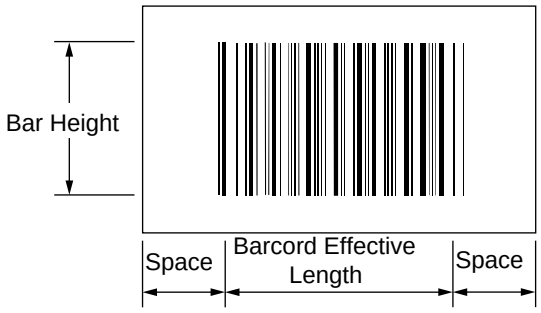


Dimensions of Barcode Label

(a) The leading and trailing spaces should be greater than or equal to 5 mm.

(b) The effective length of bars should be less than or equal to 40 mm. This length is related to the ease of placing the label. The physical absolute maximum length is 48 mm.

(c) The bar height should be greater than or equal to 20 mm. This height is theoretically required to be at least 10 mm to scan lines. However, a label of which bar height is only 10-20 mm may cause problems as the tube may rotate to sufficiently prevent the instrument from reading the barcode.



(d) For rack label, the bar height should be 6 mm or greater.

Revised January 2003 - 2.0_en

Check-Digit

The barcode ID system requires the check-digit(s) to be added on the barcode label to improve the reliability of the ID number.

(A) Modulus 10/Weight 3

This Modulus 10/Weight 3 method is used in the barcode symbology such as JAN/EAN/UPC, NW-7 and ITF (Interleaved 2 of 5). Check digit computation method is shown as follows;

1. The least significant digit (right most digit) and all digits that occur on the odd position from right to left within the data digits are defined as odd digits. All the digits are divided into two groups, odd digits and even digits.
2. Add all odd digits. Multiply the sum by 3.
3. Add all even digits.
4. Add the result of (2) and result of (3) above.
5. Subtract the foremost (least significant) digit from 10 to obtain the check-digit. In case of the ITF, the total number of the digits must be an even number. In such case, add “0” to the most significant digit (left most digit).

Example No. 1:

Calculation of the check-digit for the JAN code 4912345 (7 digits) is shown below:

1. Add odd digits (counted from the least significant digit): 5 + 3 + 1 + 4 = 13.

   Multiplied the sum by 3, as: $13 \times 3 = 39$
2. Add even digits: 4 + 2 + 9 = 15
3. Add the results of (1) and (2) above, as: 39 + 15 = 54
4. Check-digit is obtained by subtracting the right most digit of the sum of (3) above from 10 as: 10 - 4 = 6

   Hence the check-digit is 6.

Example No. 2:

Calculation of the check-digit for the ITF code 524362 (6 digits) is shown below:

1. Add odd digits : 2 + 3 + 2 = 7.

   Multiplied the sum by 3, as: $7 \times 3 = 21$
2. Add even digits: 6 + 4 + 5 = 15
3. Add the results of (1) and (2) above, as: 21 + 15 = 36
4. Obtain the check-digit as: 10 - 6 = 4

   Hence the check-digit is 4.

However, in Example No. 2, the sum of the total number of the data digits and the check-digit gives odd number 7 in this case. Therefore, “0” is added to the most significant digit (left most digit) and check-digit is appended to the data, as 05243624.

Revised January 2003 - 2.0_en

(B) Modulus 11

This Modulus 11 method is used in the barcode symbology such as CODE-11, NW-7 and CODA-BAR. Check digit computation method is shown as follows:

The following example uses the ID number 15-2345-6789.

1. Weight is multiplied to each digit as:

ID Number	1	5	-	2	3	4	5	-	6	7	8	9
	×	×	×	×	×	×	×	×	×	×	×	×
Weight	3	2	1	10	9	8	7	6	5	4	3	2
	3	10	0	20	27	32	35	0	30	28	24	18

   The weight of the ID number is 3, 2, 1, ... 6, 5, 4, 3, 2 is applied to each one from the least significant to the most significant digit. The position of the check-digit is in the least significant digit of the ID number and its weight is 1.

2. Add each product as given below:

   Sum = 3 + 10 + 0 + 20 + 27 + 32 + 35 + 0 + 30 + 28 + 24 + 18 = 227

3. Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

   227/11 = 20; remainder = 7,

   11 - 7 = 4,

   Hence the check-digit is 4.

   Note that all symbols other than numbers are calculated as zero(0). The check-digit will be zero (0) when the resulted check-digit is 10 or 11.

4. This check digit is appended to the ID number;

   the barcode label is now 15-2345-67894.

5. When the ID Reader reads this barcode label, the instrument computes the check-digit(s) and recognizes the read as a valid read if the remainder is 0 or 1.

(C) Weighted Modulus 11

This Weighted Modulus 11 method is used in the barcode symbology such as NW-7 and CODA-BAR. Check-digit computation method is shown as follows:

The following example uses the ID number 15-2345-6789.

1. Weighted Modulus-11 has two sets of the weight:

   The first weight set is 2, 6, 3, 5, 4, 8, 7, 10, 9, 5, 3, 6

   The second weight set is 9, 5, 8, 6, 7, 3, 4, 10, 2, 6, 8, 5

   Each digit is applied to one digit of the ID number, from the least significant to the most significant digit. The second weight set is used when the check digit is computed to “10” as the result of using the first weight set. All symbols are assumed 0 (zero) in the calculation. Therefore, the first weight set is multiplied to each digit as given below:

Revised January 2003 - 2.0_en

NOTE: The weight for the 13th, 14th and 15th digit is 0 (zero).

ID Number	1	5	-	2	3	4	5	-	6	7	8	9
	×	×	×	×	×	×	×	×	×	×	×	×
Weight	6	3	5	9	10	7	8	4	5	3	6	2
	6	15	0	18	30	28	40	0	30	21	48	18

2. Add each product as given below:

   Sum = 6 + 15 + 0 + 18 + 30 + 28 + 40 + 0 + 30 + 21 + 48 + 18 = 254

3. Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

   254/11 = 23; remainder = 1,

   11 - 1 = 10,

   The check-digit is now computed by using the second weight set as:

ID Number	1	5	-	2	3	4	5	-	6	7	8	9
	×	×	×	×	×	×	×	×	×	×	×	×
Weight	5	8	6	2	10	4	3	7	6	8	5	9
	5	40	0	4	30	16	15	0	36	56	40	81

4. Add each product as given below:

   Sum = 5 + 40 + 0 + 4 + 30 + 16 + 15 + 0 + 36 + 56 + 40 + 81 = 323

5. Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

   323/11 = 29; remainder = 4,

   11 - 4 = 7,

   Hence the check-digit is 7.

6. This check digit is appended to the ID number;

   the barcode label is now 15-2345-67897.

7. When the ID Reader reads this barcode label, the instrument computes the check-digit by using the first weight set and recognizes the read as a valid read if the remainder is 0. If the remainder is not 0, the instrument computes the check-digit by using the second weight set and recognizes the read as a valid read if the remainder is 0.

Revised January 2003 - 2.0_en

(D) Modulus 16

The Modulus 16 is the check-digit computation method used in NW-7 and CODABAR symbologies. Since the NW-7 and CODABAR symbologies use 4 kinds of start/stop codes, these start/stop codes are computed from the data digits.

The following example uses the ID number D998147D.

1. Add the values of all the data characters including the start and stop codes. The numerical value of each of the data character is given below:

Character	Value	Character	Value	Character	Value
0	0	7	7	.	14
1	1	8	8	+	15
2	2	9	9	A	16
3	3	-	10	B	17
4	4	$	11	C	18
5	5	:	12	D	19
6	6	/	13		

   Sum = 19 + 9 + 9 + 8 + 1 + 4 + 7 + 19 = 76

2. Divide the sum by 16 and get the remainder. Then subtract the remainder from 16. The result is the check-digit. When the remainder is 0, check-digit becomes 16. In such a case set the check-digit to “0”.

   76/16 = 4; remainder = 12,

   16 - 12 = 4,

   Hence the check-digit is 4.

3. This check-digit is appended to the left of the stop code in the ID number; the barcode label is now D9981474D.

4. When the ID Reader reads this barcode label, the instrument computes the check-digit and recognizes the read as a valid read if the remainder is 0.

(E) Modulus 43

Modulus 43 is the check digit computation method used in CODE-39 symbology. Each of 43 characters is assigned each value. All characters are converted into the value and computed.

The following example uses the ID number 258-416.

1. Add the values of all the data characters. The numerical value of each of the data characters is given below:

Character	Value	Character	Value	Character	Value
0	0	F	15	U	30
1	1	G	16	V	31
2	2	H	17	W	32
3	3	I	18	X	33
4	4	J	19	Y	34

Revised January 2003 - 2.0_en

Character	Value	Character	Value	Character	Value
5	5	K	20	Z	35
6	6	L	21	-	36
7	7	M	22	.	37
8	8	N	23	Space	38
9	9	O	24	$	39
A	10	P	25	/	40
B	11	Q	26	+	41
C	12	R	27	%	42
D	13	S	28		
E	14	T	29		

Sum = 2 + 5 + 8 + 36 + 4 + 1 + 6 = 62

2. Divide the sum by 43 and get the remainder.

   62/43 = 1; remainder = 19

3. Find the check-character. The check-character is that character whose value is equal to the remainder. In this example, the letter “J” has the value of 19 which is equal to the remainder. Therefore “J” is the check-character.

4. This check-character is appended to the ID number, after the least significant digit. The bar-code label is now “258-416J”.

(F) Modulus 103

Modulus 103 is the check-digit computation method used in CODE-128 symbology.

CODE-128 takes three different character table depending on the start code. Each of 128 characters is assigned a value as shown in the following table. All characters are then converted to their corresponding values and computed.

1. All characters except the stop code are converted to their corresponding values according to the table.
2. The first character, such as “Start (Code A)”, indicates that the Code A set is used until other code set is specified. Multiply the most significant digit by 1, multiply the second digit by 2, multiply the third digit by 3, and so on.
3. Add all the products.
4. Divide the sum by 103.
5. Convert the remainder to the corresponding character in the table. This is the check-digit.

Revised January 2003 - 2.0_en

The following example uses the ID number Start (Code A) 123-4567.

1. Convert each character into values using Code A set, and multiply by the weight.

   Start (Code A)103 = 103

   1 $17 \times 1 = 17$

   2 $18 \times 2 = 36$

   3 $19 \times 3 = 57$

   - $13 \times 4 = 52$

   4 $20 \times 5 = 100$

   5 $21 \times 6 = 126$

   6 $22 \times 7 = 154$

   7 $23 \times 8 = 184$

2. The sum of the products is 829.
3. This sum is divided by 103 as; 829/103 = 8 and remainder is 5.
4. The corresponding character for the value 5 is %. Hence the check-digit is %.

Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
0	(space)	(space)	00	54	V	V	54
1	!	!	01	55	W	W	55
2	“	“	02	56	X	X	56
3	#	#	03	57	Y	Y	57
4	$	$	04	58	Z	Z	58
5	%	%	05	59	[	[	59
6	&	&	06	60	\	\	60
7	'	'	07	61	]	]	61
8	(	(	08	62	^	^	62
9	)	)	09	63	_	_	63
10	*	*	10	64	NUL	`	64
11	+	+	11	65	SOH	a	65
12	,	,	12	66	STX	b	66
13	-	-	13	67	ETX	c	67
14	.	.	14	68	EOT	d	68
15	/	/	15	69	ENQ	e	69
16	0	0	16	70	ACK	f	70
17	1	1	17	71	BEL	g	71
18	2	2	18	72	BS	h	72
19	3	3	19	73	HT	i	73
20	4	4	20	74	LF	j	74
21	5	5	21	75	VT	k	75

Revised January 2003 - 2.0_en

Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
22	6	6	22	76	FF	l	76
23	7	7	23	77	CR	m	77
24	8	8	24	78	SO	n	78
25	9	9	25	79	SI	o	79
26	:	:	26	80	DLE	p	80
27	;	;	27	81	DC1	q	81
28	<	<	28	82	DC2	r	82
29	=	=	29	83	DC3	s	83
30	>	>	30	84	DC4	t	84
31	?	?	31	85	NAK	u	85
32	@	@	32	86	SYN	v	86
33	A	A	33	87	ETB	w	87
34	B	B	34	88	CAN	x	88
35	C	C	35	89	EM	y	89
36	D	D	36	90	SUB	z	90
37	E	E	37	91	ESC	{	91
38	F	F	38	92	FS	|	92
39	G	G	39	93	GS	}	93
40	H	H	40	94	RS	~	94
41	I	I	41	95	US	DEL	95
42	J	J	42	96	FNC3	FNC3	96
43	K	K	43	97	FNC2	FNC2	97
44	L	L	44	98	SHIFT	SHIFT	98
45	M	M	45	99	CODE C	CODE C	99
46	N	N	46	100	CODE B	FNC4	CODE B
47	O	O	47	101	FNC4	CODE A	CODE A
48	P	P	48	102	FNC1	FNC1	FNC1
49	Q	Q	49	103	START (Code A)		
50	R	R	50	104	START (Code B)		
51	S	S	51	105	START (Code C)		
52	T	T	52		STOP		
53	U	U	53				

Applicable Characters

The valid characters for the ID barcode system are numerals (0-9) and a hyphen (-).

CODABAR (NW-7) and CODE-39 may use the other characters such as alphabets, however the instrument ID system does not recognize them. The ID number allows up to thirteen digits. The application of hyphens in an ID number should adhere to the following rules:

1. Hyphens must be placed between other characters.
2. The ID number cannot begin or end with a hyphen.
3. Hyphens are included as part of the allowable maximum number of 13 characters.
4. When calculating check character of an ID number that includes hyphens, the hyphen in CODABAR (NW-7) is calculated as 0 (zero), and hyphen in CODE-11 is calculated as 10 in decimal. In the CODE-39 symbology, the hyphen is calculated as 0 (zero) for Modulus 11, and as 36 for Modulus 43.
5. ITF cannot recognize the hyphen since this symbology does not allow such a character.

Effective Barcode Length

For the NW-7 (CODABAR) and CODE-39 symbologies, the ID number can consist a minimum of 1 digit, and a maximum of 13 digits. For the other symbologies, the minimum number of digits depends on the symbology used and the application of the check-digit.

Quality Control Barcode Label

The instrument performs quality control by using the auto sampler. When using this program, the barcode label is prescribed by the following:

CODABAR (NW-7)

The CODABAR (NW-7) employs the start/stop codes “a”, “b”, “c”, or “d”. The instrument defines the ID number as the quality control data when the ID number is sandwiched by two start/stop codes of “c” and has the same number in each digit.

For example, the ID number “c11111111c” is read as “File No. 1” of the quality control program.

CODE-128

CODE-128 employs alphabetical characters. Therefore, the instrument defines the ID number as quality control data when the ID number is read as “QC-” and is followed by 8-digit Lot number.

Affixing Barcode Label

Refer to “5.10 Prepare Samples” for the correct barcode label position.

Revised January 2003 - 2.0_en