To Cover

SECTION 1 SPECIFICATIONS

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1.1 NAME AND MODEL NUMBER

Name: Automated Hematology Analyzer
3 Models: KX-21
KX-21N

1.2 SYSTEM ORGANIZATION

3

	KX-21	KX-21N
Main Unit	KX-21 Main Unit	KX-21N Main Unit
1 **Built-in printer (IP)**	Standard equipment	Standard equipment
RS-232C serial interface	Option	Standard equipment
Graphic printer (GP/LP)	- - -	Option
Data printer (DP)	- - -	Option
Hand-held type bar code reader	- - -	Option
Serial/LAN adapter	- - -	Option

1.3 ELECTRICAL RATINGS

1.3.1 Rated Voltage

Input Voltage:
AC 100V, 117V, 220V, 230V, 240V ± 10%

Output Voltage:

DC ±15 ± 0.75 V	0.5 A
DC +100 ± 3 V	0.02 A
DC +15 ± 0.1 V	2.0 A
DC +12 ± 0.2 V	3.0 A
DC +24 ± 1.2 V	0.7 A
AC 100 V	1.2 A

Rated Voltage:
AC 100V, 117V, 220V, 240V ± 10%

The KX-21 supports two types of power supplies (100 V and 200 V).
The input voltage can be switched between 100 V and 117 V, or between 220 V and 240 V, depending on the power supply's internal settings.

1.3.2 Line Frequency

50 Hz or 60 Hz

1.3.3 Power Consumption

230 VA or less

1.4 DIMENSIONS AND WEIGHT

Dimensions: 420 (W) x 355 (D) x 480 (H) mm
Weight: Approx. 28 kg (KX-21)
Approx. 30 kg (KX-21N) 3

NOTE: The acceptable dimensional difference is within 3% of the values listed above. Protrusions are not included in the above dimensions. The acceptable weight difference is within 10% of the values listed above.

1.5 INTENDED USE

The KX-21 is intended *for in vitro diagnostic use*, analyzing 18 parameters in anti-coagulated human blood.
The anti-coagulants are EDTA-2K, EDTA-3K and EDTA-2Na. The Anti-coagulant volume conforms to NCCLS standards.

1.6 PERFORMANCE SPECIFICATIONS

1.6.1 Analysis and Display Range

(1) Analysis Range

WBC: 1.0 - 99.9 x 10^3/µL
RBC: 0.30 - 7.00 x 10^6/µL
HGB: 0.1 - 25.0 g/dL
HCT: 10.0 - 60.0%
PLT: 10 - 999 x 10^3/µL

(2) Display Range

WBC:	0 - 299.9 x 10^3/µL
RBC:	0 - 19.99 x 10^6/µL
HGB:	0.0 - 25.0 g/dL
HCT:	0.0 - 99.9%
MCV:	0.0 - 299.9 fL
MCH:	0.0 - 99.9 pg
MCHC:	0.0 - 99.9 g/dL
PLT:	0 - 1999 x 10^3/µL
W-SCR or LYMPH%:	0 - 100.0%
W-MCR or MXD%:	0 - 100.0%
W-LCR or NEUT%:	0 - 100.0%
W-SCC or LYMPH#:	0 - 299.9 x 10^3/µL
W-MCC or MXD#:	0 - 299.9 x 10^3/µL
W-LCC or NEUT#:	0 - 299.9 x 10^3/µL
RDW-CV:	0.0% - 100.0%
RDW-SD:	0 - 250 fL
PDW:	0 - 40.0 fL
MPV:	0 - 40.0 fL
P-LCR:	0 - 100.0%
WBC Histogram	0 - 300 fL
RBC Histogram	0 - 250 fL
PLT Histogram	0 - 40 fL

1.6.2 Accuracy

When control blood or calibrator is analyzed 10 times consecutively, the mean difference from the value obtained on the standard instrument should be within the following range:

• Whole Blood Mode

WBC	Within ± 3% or ±0.2 x 10^3/µL
RBC	Within ± 2% or ±0.03 x 10^6/µL
PLT	Within ± 5% or ±10 x 10^3/µL

• Pre-diluted Mode

WBC	Within ± 5% or ±0.3 x 10^3/µL
RBC	Within ± 3% or ±0.05 x 10^6/µL
PLT	Within ± 8% or ±15 x 10^3/µL

1.6.3 Reproducibility

When fresh normal blood or control blood is analyzed in Whole Blood mode 10 times consecutively, the variation of coefficient under 95% confidence interval should be within the following range:

Parameter	Condition	Whole Blood Mode	Pre-diluted Mode
WBC	WBC 4.0 x 10^3/µL or more	3.5% or lower	6.0% or lower
RBC	RBC 4.00 x 10^6/µL or more	2.0% or lower	3.0% or lower
HGB		1.5% or lower	2.5% or lower
HCT		2.0% or lower	3.0% or lower
MCV		2.0% or lower	3.0% or lower
MCH		2.0% or lower	3.0% or lower
MCHC		2.0% or lower	3.0% or lower
PLT	PLT 100 x 10^3/µL or more	6.0% or lower	9.0% or lower
W-SCR		15.0% or lower	25.0% or lower
W-MCR	W-MCR 12% or more	30.0% or lower	45.0% or lower
W-LCR		15.0% or lower	25.0% or lower
W-SCC		15.0% or lower	25.0% or lower
W-MCC	W-MCC 1.0 x 10^3/µL or mroe	30.0% or lower	45.0% or lower
W-LCC		15.0% or lower	25.0% or lower
RDW-CV		4.0% or lower	6.0% or lower
RDW-SD		4.0% or lower	6.0% or lower
PDW		12.0% or lower	18.0% or lower
MPV		5.0% or lower	7.5% or lower
P-LCR		20.0% or lower	30.0% or lower

1.6.4 Linearity

When the whole blood manual mode analysis is executed, the difference from the theoretical value should be within the following range:

WBC:	1.0 - 99.9 x 10^3/µL	(Within ±0.3 x 10^3/µL or ± 3%)
RBC:	0.30 - 7.00 x 10^6/µL	(Within ±0.03 x 10^6/µL or ± 3%)
HGB:	0.1 - 25.0 g/dL	(Within ±0.2 g/dL or ± 2%)
HCT:	10.0 - 60.0%	(Within ±1.0 HCT% or ± 3%)
PLT:	10 - 999 x 10^3/µL	(Within ±10 x 10^3/µL or ± 5%)
	(When RBC<7.00 x 10^6/µL)	

1.6.5 Carryover

When normal fresh blood or control blood is analyzed, the carryover rate obtained by standard analysis should be within the following range:

WBC	3% or less
RBC	1.5% or less
HGB	1.5% or less
HCT	1.5% or less
PLT	5% or less

1.6.6 Stability

When normal fresh blood or control blood is analyzed, the stability should be within the following range:

(1) Stability relative to Temperature

In normal fresh blood or control blood analysis, the data fluctuation while the ambient temperature changes from 15°C to 30°C should be within the following range:
The following data are based on the assumption that the sample is analyzed within 12 hours after collection, and that any change in the sample should be excluded from the fluctuation ratio.

WBC	Within 10% or 0.05 x 10^3/µL
RBC	Within 5%
HGB	Within 5%
HCT	Within 5%
PLT	Within 15% or 30 x 10^3/µL

(2) Within-a-Day Stability

In control blood analysis of 5°C or less ambient temperature change, the data fluctuation for 24 hours after startup should be within the following range:

WBC	Within 10%
RBC	Within 5%
HGB	Within 5%
HCT	Within 5%
PLT	Within 15% or 30 x 10^3/µL

(3) Day-to-Day Stability

In control blood analysis of 5°C or less ambient temperature change, the data fluctuation for ten days should be within the following range:

WBC	Within 10%
RBC	Within 5%
HGB	Within 5%
HCT	Within 5%
PLT	Within 15% or 30 x 10^3/µL

(4) Stability relative to Power Supply Voltage

In control blood analysis of 5°C or less ambient temperature change, the data fluctuation while the power supply voltage changes 10% from the rated voltage should be within the following range:

WBC	Within 10%
RBC	Within 5%
HGB	Within 5%
HCT	Within 5%
PLT	Within 15% or 30 x 10^3/µL

1.6.7 Throughput

Approx. 60 seconds/sample
Approx. 60 samples/hour

1.6.8 Required Sample and Reagent Volumes

	Whole Blood Mode	Pre-diluted Mode	Shutdown
Sample Volume	approx. 50 µL	approx. 20 µL (200 µL of 1:26 diluted sample is aspirated.)	- - -
Diluent	approx. 34 mL/sample	approx. 34 mL/sample	approx. 200 mL/ cycle
Lyse reagent	approx. 1.0 mL/sample	approx. 1.0 mL/sample	approx. 5 mL/ cycle
Detergent	- - -	- - -	approx. 0.3 mL/cycle

1.6.9 Graphic LCD/Panel Keyboard

1.6.9.1 Graphic LCD Panel Display
- 320 x 240 dots (dot pitch: 0.36 x 0.36 mm)
- With backlight
- Display Area: 115.17 x 86.37 mm

1.6.9.2 Graphic LCD Display Items
- Date/Time
- Sample ID No.
- Analysis results including flag
- Error messages
- Instrument status
- Service data
- Select Menu
- Analysis mode

1.6.9.3 Used Languages
- Panel Keyboard English
- LCD Display English, Chinese, or Japanese *German, French, Spanish, Italian, Portuguese are available on KX-21N 3
- Printer English
- Label English, Chinese or Japanese

1.6.10 Sample ID Number

6-digit number (KX-21)
15-digit number (KX-21N) 3

1.7 FUNCTIONS

1.7.1 Data Storage

(1) Analysis Results: 240 samples without histograms (KX-21)
300 samples with histograms (KX-21N) 3
(2) Histograms: None
(3) Quality Control Data: 60 points (in 6 files)
(4) Setting Values
(5) Maintenance Data
1) Instrument Operation Cycle Count
2) Unit Operation Cycle:
Stores the number of operations after the replacement or maintenance of Waste Chamber, Detector and SRV.
3) Error History:
Can be output to host computer, but not displayed on LCD.

1.7.2 Printer

1.7.2.1 Built-in Printer Specifications
- Thermal printer
- Model: FTP-421MCL001 (Compatible with K-4500/F-820)
- Control board: PCB No. 6350
- Thermal paper, 60 mm width

1.7.2.2 Printed Items

	IP (built-in printer)	DP	GP	LP
Date/Time	Print	Print	Print	Print
Sample ID No.	Print	Print	Print	Print
Analysis results including flag	Print	Print	Print	Print
Histograms	Print	Not print	Print	Not print
QC data	Print	Not print	Print	Print
QC chart	Not print	Not print	Print	Not print
Setting values	Print	Not print	Print	Not print
Service data	Print	Not print	Not print	Not print

NOTE: DP, GP and LP are available for KX-21N only. 3

1.7.3 Serial Interface

1 port of RS-232C Serial Interface is provided to output the following data to host computer.
- The latest analysis results
- Stored data
- QC data

1.7.4 Histogram Analysis

Discriminator position on the latest analysis can be manually changed.

1.7.5 Quality Control

- $\overline{X}$ Control or L-J Control

  Up to 60 points of control data can be stored for 6 types of samples (in 6 files).
  Up to 21 control parameters can be selected. (For N.A. market: up to 17 parameters.)
  The control limit can be manually set.
  Sample for quality control: EIGHTCHECK-3WP, EIGHTCHECK-EXTRA (N.A. market only),
  EIGHTCHECK-C (Chinese market only) 3

1.7.6 Calibration

1.7.6.1 Customer Calibration

1) Calibration Method:	Manual calibration, Auto calibration
2) Calibration Mode:	Whole Blood Mode
3) Calibration Parameters:	WBC, RBC, HGB, HCT, PLT (N.A. market only) HGB, HCT (Other markets)
4) Calibration Samples:	Fresh normal blood samples SCS-1000 (N.A. market only)

1.7.6.2 Factory Calibration

Calibration is performed with the same method as the service calibration, using 3WP-REFERENCE MATERIAL.

1.7.7 Abnormality Detection Function

1.7.7.1 Error Alerting Function

Monitors the abnormalities in the followings, and alert with error messages with alarm when any abnormality is detected.

(1) Hydraulic System and Mechanical System
- Reagent level in the internal reservoir chambers
- Fluid level in the waste chambers
- Pressure and vacuum
- Rinse cup operation
- Others

(2) Analysis Condition
- Sampling data
- HGB detection
- Temperature
- Clog

(3) Electricity
- Sub-processor operation
- External device connection
- Built-in printer connection
- Built-in printer paper

(4) Others
- Calibration
- Quality Control

1.7.7.2 Histogram Abnormality

Monitors the abnormalities in the histograms, and add a flag to abnormal data. Refer to the Operator's Manual for the details.

(1) WL, RL, PL: Relative height at Lower Discriminator exceeds the preset limit.
(2) WU, RU, PU: Relative height at Upper Discriminator exceeds the preset limit.
(3) DW: The RBC histogram does not cross the 20% height level twice.
(4) MP: Two or more peaks exist in RBC or PLT histogram.
(5) T1: The trough discriminator cannot be set between SCR and MCR populations.
(6) T2: The trough discriminator cannot be set between MCR and LCR populations.
(7) F1, F2, F3: Relative height at the trough discriminator exceeds the preset limit.
(8) AG: Too many cells exist at WBC Lower Discriminator and lower 2 channels.

1.7.7.3 Analysis Results Abnormality

Monitors the abnormalities in the analysis results, and add a flag to abnormal data. Refer to the Operator's Manual for the details.

(1) + or –: An analysis result exceeded the preset Patient Mark Limit.
(2) *: An analysis result exceeded the Linearity Limit.

1.7.7.4 Imitation Reagents

Reagent specification is monitored as below.

(1) Diluent
Monitors the conductivity of diluent if it differs 10% or more compared with that of CELLPACK.
When abnormality is detected, alert with error message "RBC Analysis Error".

(2) Lyse reagent
Monitors WBC histogram if mono-peak or two-peak histogram is detected for 11 consecutive samples.
When abnormality are detected, alert with error message "WBC Analysis Error".

The data reporting when abnormality is detected can be set by DIP SW in two levels:
• Level 1: The related data will not be displayed.
• Level 2: The related data will be displayed with an asterisk (*).

1.8 START-UP

(1) System Check including position initialization of mechanical parts.

(2) Auto Rinse

(3) Background Check
The background check limit is as follows: The background check can be repeated up to three times.

WBC $< 0.3 \times 10^3/\mu L$
RBC $< 0.02 \times 10^6/\mu L$
HGB < 0.1 g/dL
PLT $< 10 \times 10^3/\mu L$

1.9 SHUT DOWN

The hydraulic system is cleaned with diluted CELLCLEAN aspirated from the whole blood pipette.
To shut down the system, press the [Shutdown] key.

1.10 MAINTENANCE

(1) Customer maintenance
1) Reagent replacement sequence
2) Auto rinse with background check sequence
3) Settings sub-menu for customer system set up
4) Waste chamber cleaning sequence
5) Transducer cleaning sequence
6) Transducer fluid draining sequence (for clog removal)
7) Status display
- HGB convert (real time)
- Pressure and vacuum (real time)
- Unit operation counter

8) Paper feed (optional built-in printer)

(2) Special Sequences (Service purpose only)
1) Clog removal
2) Setting sequence (Install)
3) Deprime sequence
4) Gain adjustment
5) Control mode
6) Calibrator mode
7) Continuous mode
8) Clog adjustment
9) Initialize/Change/Print setting values

(3) Special Sequences (Production & R&D purpose only)
1) Factory rinse sequence
2) Shipping sequence
3) Factory initialize/Factory settings
4) Raw data output
5) Debugger

(4) Test Operation (Service purpose only)
1) Diaphragm test operation
2) SV test operation
3) HC output test (optional)
4) Built-in printer output test (optional)

(5) Service Information Display (Service purpose only)
1) Temperature
2) Operation status
3) Sampling data
4) Service data

(6) Program Device
1) EEPROM (KX-21)
2) Flash memory card (KX-21N) 3

1.11 SAFETY PROTECTION

Main Unit Power Supply : Fuse

1.12 ACOUSTIC NOISE

55 dB or less

1.13 ENVIRONMENTAL REQUIREMENTS

(1) Ambient Temperature: 15 - 30°C
(The reagent temperature should also be within this range.)
(2) Relative Humidity: 30% - 85%
(3) Atmospheric Pressure: 70 - 106 kPa
(4) Installation Condition: Avoid installation in a place where the instrument may be exposed to direct sunlight, dust, vibration or acid.

1.14 REAGENTS

Diluent: CELLPACK
Lyse reagent: STROMATOLYSER-WH
Detergent: CELLCLEAN

NOTE: See Section 1.6.8 for reagent consumption.

1.15 STORAGE CONDITIONS

< Instrument >
(1) Ambient Temperature: between -10 and +60°C
(2) Relative Humidity: 30% - 95%, No dew condensation
(3) Atmospheric Pressure: 70 - 106 kPa

< Reagent >
Refer to the instructions on the package insert or container for the storage of each reagent.