

Model YR05117 Semi-auto Coagulation Analyzer Instruction Manual

Thank you very much for purchasing our Semi-auto Coagulation Analyzer Model YR05117.

Please read the "Operating Instructions" and "Warranty" before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the "Warranty" at a hand place for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

https://kalstein.net/



ourservices Benefits and Support

In Kalstein France, we take care of the full satisfaction of our customers, that is why we provide value-added services of the highest level based on our experience.



Ø

Online Inductions and Trainings

In any part of the world, receive your induction or training from our specialized team of engineers



Quick Response Our work team is always available to response all your consults or questions, in order to support you in any situation.



#Letsgivemore Thanks to your purchase, a donation will be made to a non-profit foundation that fights against breast cancer and helps most vulnerable communities.



Technical Support Enjoy of personalized advice for the correct preventive and corrective maintenance of your equipment.

correct preventive and corrective maintenance of your equipment, thanks to Kalstein's manuals and articles, special catalogues and video tutorials.







Delivery Logistics We take care of all the necessary logistics for the dispatch of your goods, whether is by sea, land or.air.



Kalstein Worldwide

With more than 25 years growing with our customers, Kalstein's multiformat and modern content, is now present in more than 10 countries and increasing.



 \mathbf{Q}

CATALOGUE

First chapter: Outline	
First section: Outline2	
Second section: Device introduce 3	
Third section: Assembly attention thing 4	
Second chapter: Menu	
First section: Test Sample	5
Second section: Report	3
Third section: Edit test 10	
Fourth section: Q.C report 12	
Fifth section: Date & time 12	
Six section: Maintains 13	
Third chapter: Daily use and defend	
First section: Basically operating 15	
Second section: Daily to defend and maintain 16	
Third section: Usual breakdown and attention 17	
App1: English character input method 17	
App2: Print paper installation method	17

First Chapter OUTLINE

First section OUTLINE

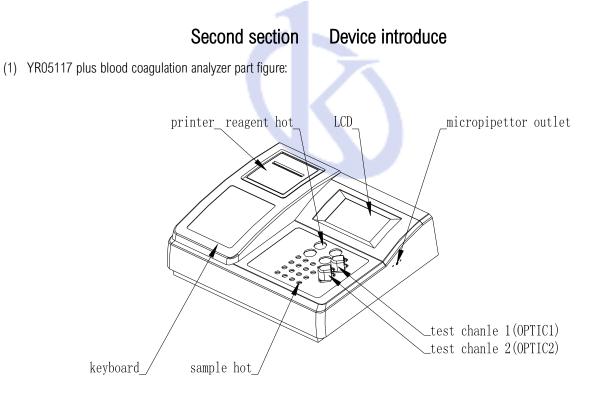
YR05117 blood coagulation analyzer is test blood coagulation parameter system. The theory is based on optical colorimetry. After reagent and plasma mixed, Fibrinogen change into fibrin, optical density of the mixture been changed and the coagulation parameter is tested. It can test a lot of items, some items list:

Prothrombin Time	PT
Activated Partial Thromboplastin Time	APTT
Fibrinogen	FIB
Thrombin Time	TT

Specification:

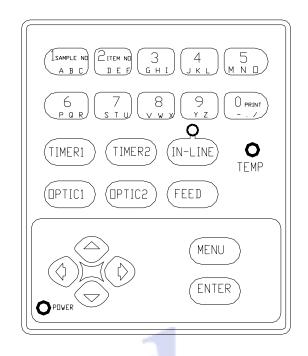
Advanced optical system, it make test result more precise; Large LCD screen; Reagent consume less than 20uL;

·built-in printer, result can be saved forever.



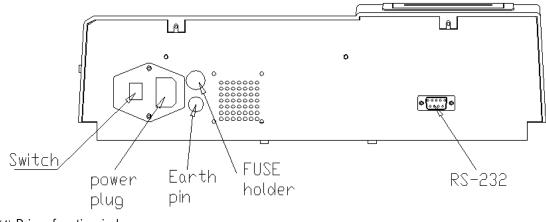
(2) Operation interface catalogue:

(À



TEMP indication lamp--- indication temperature of test channel, lamp bright display temperature of test channel is controlled 37°±0.3°C;

0-9 DIGITAL	input parameter;	
A- Z letter	input patient information;	
OPTIC1~2	activate optics test channel;	
TIMER1~2	software timer start;	
MENU	MENU select;	
ENTER	enter;	
IN-LINE	printer in-line. After press the key, lamp bright, printer is in waiting for	printing;
FEED	paper feed .	
(3) Device Back		



(4) Prime function index:

https://kalstein.net/

Sample hot place :	16pcs
Reagent hot place:	4pcs
Software timer:	2pcs
Test channel number:	2pcs
Store:	10000 test result
Test wavelength:	470nm
Temp control precision:	37±0.3°C
Reagent consume:	20ul-40uL
Notation of Result:	S, % , PTR, INR, g/L
Power:	220VAC±15% 50-60HZ
Dimension:	370mm(L)×330mm(W) ×120mm(H)
work environment:	temperature 15°C-30°C wet≤90%
mass:	6Kg

Third section Device Assembly Attention

YR05117 blood coagulation analyzer is expensive electron device. before assembly please look at flowing thing:

- a. Worktable must be horizontal. The analyzer not directly face fan and air-condition and sun light, it infect temperature control and test precision;
- b. it must be avoided libration.
- c. give off a lot of dust.
- d. power supply, frequency must be in natural range.

Second Chapter MENU

Power on the YR05117 coagulation analyzer, after self-check, screen display as flowing:

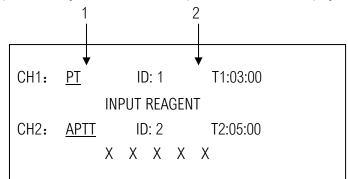
1 - TEST SAMP	4 – QC REPORT
2 - REPORT	5 – DATE&TIME
3 – EDIT TEST	6 - MAINTAINS

Daily working often use menu 1, 2. Menu 1 --- sample test; Menu 2 may be report.

First section Test Sample

After turn on power switch 10—20-minute, TEMP indication lamp light, temperature of test channel is controlled $37^{\circ}\pm 0.5^{\circ}C$; The analyzer can test.

In main menu, press "1" key, enter into test sample menu, screen display:



- (1) Press"2" key, 1 position appear cursor, enter test code No
- (2) Press"1" key, 2 position appear cursor, enter patient No.
- (3) Place hot sample cup into test cannel, sample pipette absorb the corresponding hot reagent in advance quantity; Press "OPTIC1~OPTIC2" key, input reagent in the place that shows XXXXX on screen. Right now, along sample cup wall, notice to move sample pipette to press after all by addition of reagent, loosen open to move sample pipette, instrument begins test voluntarily. After test is completed, device sends sound, corresponding test end also display in XXXXX place trip.

Above-mentioned (1)-(3) item have no priority order, operator can carry out according to self habit.

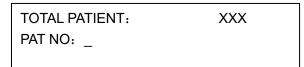
- (4) When warming up sample or reagent, press "TIMER" key starts software hourmeter T1, warm up time display on screen.
- (5) Test over, press "MENU" key and return 。
- (6) Patient invalid NO is 0, then test over, device not save result, not print.
- (7) Test over , please return main interface first, then press " 2 " key carry out corresponding operation, print the result.

Second section REPORT

Under main menu, press "2" key and system enter result report menu, display as flowing:

1 Edit patient file

1.1 You may enter every patient name, sex, age and blood type. system display:



You may enter patient no. (1 – 59999). Through '↓' key, use search function, after search for need ID please

press ' ENTER', if the number of direct enter store in no note, system will display:

Answer 'Y' or press 'ENTER' key, system will be found patient no. in RAM, then enter next step, answer 'N' system return

You may enter at most 12 Characters, below 12 Characters please press 'ENTER' then system display patient no. and name in the first line (Characters enter plan please refer to APP1)

SEX: input 'M' or 'F', 'M'--male, 'F'--female, you can press the '—' '— 'Key to choose it.

AGE: input 0-999, unit is 'Y' (year)

BLD TYPE: blood type A / B / O / AB. you can press the ' \leftarrow ' ' \rightarrow 'Key to choose

If you input no. that RAM have existed, then system direct display and you can modify, press 'MENU' to return.

2. Delete result

You must input in patient no., but it must be already exist, or uses search function.

TOTAL PAT	TIENT:	
PAT NO:	XXXXX	

Next system display:

PAT NO:	XXXXX	NAME:	XXXXX
TOTAL	TEST XX		
0	APTT	35.8	S
ENTER TO DEL			

'0' position direct the result is the order of patient result, 'APTT' position display is test name, '35.8' position display the result, last display is unit, you may look at with the order of ' \uparrow '' \downarrow ' key, if not need the result, press' ENTER' can delete. press 'MENU' return.

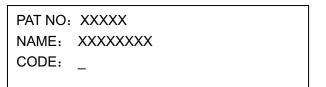
3, Add other result

Some tests in this analyzer cannot be test, must use other device, when the result must send out together, may uses this function, but must defines this test first.

System display:

TOTAL PATIENT:	XXXX
PAT NO: _	

It enter the already exist no., also may enter new no., as soon as use searches for function. Then display:



Right now, can also use the search function code ' \downarrow ' or input, but it must be the code that had defined. As system display:

PAT NO:	XXXXX		
NAME:	XXXXX	XXX	
CODE:	XX	NAME:	XXXX
RESULT:	_·		

Please enter the other result, press 'MENU' return.

4 print /delete report

1 — PRINT SEL PATIENT	
2 — PRINT ALL PAT	
3 — DEL SEL PATIENT	
4 — DEL ALL PAT	

4.1 Print report

4.1.1 Print select patient report

If you want print results of a patient, may select this function, system display:



You may input patient no (1 – 59999) , or press ' \downarrow 'key to use search function , press 'ENTER' key may print a patient report, keep 'MENU' key return.

4.1.2 Print all patient

When starting this function system display:

START DATE : _

you may enter a patient start day, then system display:

START DATE: XX XX END DATE: _ After you enter an end date that it is more than start date, system begin find all patient report in RAM, find some report accord with condition, find one print one, till print over, if want halfway stop print, must close system.

When system point out enter start date, if you want print all result in RAM, then may press 'ENTER' key, then system display:



You may press 'Y', 'N', 'menu':

Press 'Y' at once begin print all result in RAM $_{\circ}$ Press 'N' return 'start date'.

Press 'menu' return.

4.2 Delete patient report

4.2.1 Delete select report

Select this function may delete all save result of files and a result of patient report in RAM. It is similar with patient report, system display:

PAT NO:

You may input number key and may use search function, press " ENTER ' key may delete.

4.2.2 Delete all patient report

This section are completely similar with print all patient report. After delete is cannot again revive, so please use this delete function carefully.

Third section Edit Test

How to modify already exist parameter of test and add new test in this function. If develop new test or change the reagent of different manufacturer, please enter new parameter of correct reagent.

1. Edit Test

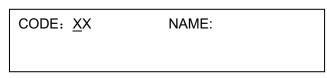
Under main menu state, press "3" key and system enter the interface of edit test, display as flowing:

DEFINE TEST
 DSPLY TEST NUMBER
 DELETE TEST

Below, introduce 3 submenus.

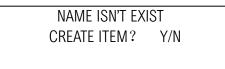
2. Define Test

The function of "DEFINE TEST ": input parameter of each test, so device can carry out test function according to correct instruction, according to following step consummately test project definition: Press "1"key, screen display:



(1) In place of XX input 1-2 digital code, code can't be 0, below two digital please press "ENTER" key. If the code has existed in system, system search it, all parameter display on screen in proper order, and cursor stops behind name. The test code no is defined as follows:1-PT,2-APTT,3-TT,4-FIB....

if the code of input not in RAM, system display:



Answer "Y", then system save, the item and enter 2 step $\$

Answer "N", System gives up this item no, and return to 'CODE:'.

(2) Input or modify test name, please enter 1 - 4 abbreviation names as: PT APTT TT.

CODE:	XX	NAME:	<u>x</u> xxx

Enter next item, press "↓" or " ENTER ".

- ③ Please use "→" or "←" select test method as " B ", " C " " O ", " B " express the coagulate method + algorithm, "C" express the coagulate method, " O " is calculated by other test, Enter next item, press " ↓" or " ENTER ".
- (4) The cursor locates behind "RESULT ": display as 'S- - -', press"↓" key, system select 'S, R, me, %, E, U' in proper order. S the second showing method, R is PTR simplified character, I INR simplified character, express international normalize ratio (INR), % percentage representation, E show absorbance value, U density representation, can select or hide the result representation of cursor place according to the key " →". Enter next item, press " ↓" or " ENTER ".

if " % " is selected in result express, then input " % -- S" standard curve (see after).

Density curve: if "u" is selected in result express, then input "C--S" standard curve (see after).

Absorbance curve: if "o" is selected in test method, then input "C -- E" standard curve (see after).

curve:

% S curve:	C – S curve:	C – E curve:
0.0 % 40.0 S	575.0 mg/dL 6.0 S	575.0 mg/dL 0.080 E
25.0 % 30.0 S	287.0 mg/dL 11.6 S	287.0 mg/dL 0.055 E
50.0 % 22.0 S	143.5 mg/dL 19.8 S	143.5 mg/dL 0.039 E
75.0 % 16.0 S	71.8 mg/dL 34.4 S	1.8 mg/dL 0.020 E
100.0 % 12.0 S	0.0 mg/dL 60.0 S	0.0 mg/dL 0.0 E

- (5) Behind" HIGH LTD:", input the high limit of normal reference value, value reference reagent manual range 1-9999 (reagent manual offer).
- (6) Behind" LOW LTD:", input the low limit of normal reference value, value reference reagent manual range 1-9999. And low limit value must be smaller than high limit value (reagent manual offer)
- (7) "TEST TIME": you can input test time as you need, normally this time is 2 times of high limit. the machine

offer the test time as follow: PT--30S; APTT-70S; TT-40S; FIB-40S.

"HOT TIME": you can input test time as you need, the machine offer the test time as follows: PT—180S; APTT—300S; TT—180S; FIB—180S.

(8) "FACTOR:" if you can test the standard sample which the result is known before, the test result is higher than the standard result, you can decrease the factor, otherwise increase the factor.

For Example:

ΡT

CODE: 1 NAME: PT METHOD: B RESULT: S-R-I----HIGH LTD: 14.0 LOW TLD: 10.0 NORMAL CONT: 12.3 ISI: 1.22 TEST TIME: 60 HOT TIME: 180 COEFFICIENT: 137 APTT CODE: 2 NAME: APTT METHOD: C HIGH LTD: 38.0 LOW TLD: 22.0 TEST TIME: 100 HOT TIME: 300 COEFFICIENT: 125

(b)

ΤT

CODE: 3	NAME:	TT
METHOD:	С	
HIGH LTD:	16.0	
LOW TLD:	8.0	
TEST: 40		
HOT TIME:	180	
COEFFICIEN	T: 77	

FIB

CODE: 4 NAME: FIB METHOD: С RESULT: U -UNIT: mg/dL HIGH LTD: 400.0 200.0 LOW LTD: CONCENTRATION CURVE: 1: 520.0 mg/dL --- 8 S 2: 400.0 mg/dL --- 10.0 S 3: 240.0 mg/dL --- 13.0 S 140.0 mg/dL --- 16.5 S 4: 5: 70.0 mg/dL --- 22.0 S TEST TIME: 40 HOT TIME: 180 COEFFICIENT: 100

3. Display test number

Select " 2 – DSPLY TEST NUMBER ", you can see total test number in RAM. Press "1", system will be reset, the change of system save any will be lost, after press "1", system can remind again, press "Y Y" if wanting to continue. When instrument manufacture, have solidified 4 test item.

4. Delete test

This section may delete test item that is not need. If the report have the test item, you must be delete the result, otherwise system will direct wrong hint.

Fourth section Q.C. REPORT

In this section you will get correct quality control result. Test quality control thing correctly, test method is as same as sample test, input this quality no. as patient no., its result must be more than frequently 3, then can print quality control result and quality control curve.

This interface is as follows:

Press'1', system select already exist test code, after determining test code, system can remind input quality control target value and deviation scope in proper order. Press '2' key, select the existed patient no. as QC no., system will look at patient no. the same as QC no., store together, manage together. If the patient no. will be used as QC no., please different from other patient no. after 1, 2 steps can carry out 3 and 4 steps, press " 3 " key, can print quality control curve, press " 4 " key can print quality result: average index, standard deviation and the quality measured control number.

Fifth Section Show Clock

To make operator know time more promptly in main menu is chosen to select the item of " 5 ", system shows that current time (use 12 hours of system or 24 hours system)

Sixth section System

This section contains 6 following contents:

1—TEMP SET	5—EDIT PAT
2—FAN SET	6—DATE&TIME
3—ADC	7—TIME MODE
4—SET PRINTER	

1. Temperature set:

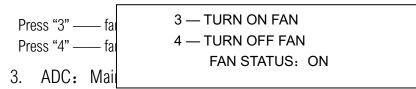
Screen display as flowing:

SET TEMP:	37.00
TEST TEMP:	36.97

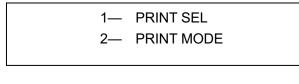
Use " \leftarrow " " \rightarrow " can set temperature as every time 1.00 °C speed adjustment, use " \downarrow " \uparrow " can set temperature as every time 0.10 °C speed adjustment

2. Fan set:

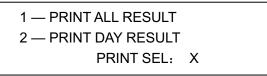
Press'2', system display as flowing:



4. Set printer:



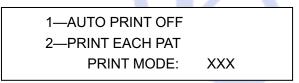
a. Print contents,



After press '1' select print all result, return to main menu 'REPORT', system will print all the patient result that owned in memory.

After press '2' select print day result, return to main menu 'REPORT', system will print the day patient result that owned in memory.

b. Print format:



XXX is one of OFF or 2.

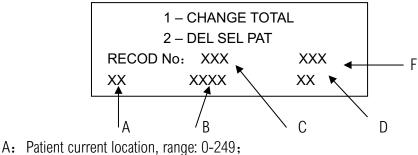
As this operation, you can select some time when print report conveniently.

(1) If not want to print report in test course, select "1" --- " OFF ';

(2) If hope that system is printing report per test over, please select "2"

5. Edit patient file:

Because of certain kind reason, the data gets influence and preservation to make mistakes in system, will affect result report if not revising.



B: Patient no, range: 1 – 9999 ;

- C: The patient number that system preserves counts, range: 1 255;
- D: The sample number that this patient preserves, range: 0 30;
- E: Patient NO. which the system have checked.

Since existing too much disturb factor, especially switch the device, maybe the patient number that system preserve is not equal to the patient number that system stored, occurs mistake. When systematic detection goes to mistake, can refer to wrong information, asks the method of clear surpass work modification to resume patient database right now, can arise wrong result otherwise in application.

6. Set date & time:

A, Time shows form: hour- minute - second XX XX XX

AM: Represent morning.

PM: Represent afternoon,

if making time format in 24 hours, XX is blank.

- B, Date shows form: year month day
- C, if not want to modify time and date, please directly press the key of 'MENU ', must not press 'ENTER' key, otherwise the correctness that can affect time is excepted if modify time.
- 7. Time format

1 — 12H FORMAT 2 — 24h FORMAT

Press '1' or '2', system change time format, if want to know time, must return main menu, press '6' key to view time and date.

8. System reset:

Because of outside or other reason system have been rushed disorder, can resume system using this function to make it default.

In the interface "MAINTAINS", press '9' five times, system can start this function, the system can still ask once:

'1' TO RESET SYSTEM '2' TO RESET PATIENT 'MENU' TO EXIT

After press '1' and 'YY', system reset. After press '2' and 'YY', the patient file will be reset. If not want reset, please press the 'MENU' key. After reset, the test result and the patient information may be lost, so please use this function carefully.

Third chapter Daily operation and defend

First section Daily operation

- 1, After turn on power switch, system carries out self check, at the same time, test cannel is heated up, after 10-20-minute, TEMP (temperature) indicator light have bright, can carry out normal test.
- 2, After operation is completed, please return to main menu, then turn off power switch. Avoid turn off power switch suddenly as testing or printing.
- 3, To help operator learn to use quickly, enumerate the operating example of parameter frequently as follows:
- A. PT test.
 - 1, Turn on power switch waiting for TEMP indicator light, sample must be revolved at 3500 rpm centrifugal as long as 10 minutes;
 - 2, Apply PT reagent (basis test amount take suitable quantity) 37 °C preheat 10 minutes;
 - 3, Add 20uL of blood plasma, warm up 3 minutes (sample will add to cup bottom, there can not be bubble) in advance;
 - 4, Put hot sample cup into test cannel, sample pipette absorb 40uL PT reagent;
 - 5, Press " OPTIC", screen display " INPUT REAGENT ", join PT reagent, (must press all hearing sound), instrument begins test;
 - 6, About 30 seconds, screen shows " + + +. + S ";
 - 7, Repeat 5-6 step can test continuously. Press "MENU", return main menu.
- B, APTT test
 - 1, Turn on power switch waiting for TEMP indicator light, sample must be revolved at 3500 rpm centrifugal as long as 10 minutes;
 - 2, Apply APTT reagent (basis test amount take suitable quantity) 37 °C preheat 10 minutes;
 - 3, Mix 20uL of blood plasma and APTT reagent, warm up 5 minutes (sample will add to cup bottom, there can not be bubble) in advance;
 - 4, Put hot sample cup into test cannel, sample pipette absorb 20uL Cacl2 reagent
 - 5, Press "OPTIC", screen display "INPUT REAGENT ", join PT reagent, (must press all hearing sound), instrument begins test;
 - 6, About 70 seconds, screen shows " + + +. + S ";
 - 7, Repeat 5-6 step can test continuously. Press "MENU", return main menu.
- C. TT test
 - 1, Turn on power switch waiting for TEMP indicator light, sample must be revolved at 3500 rpm centrifugal as long as 10 minutes;
 - 2, Apply TT reagent (basis test amount take suitable quantity) 37 °C preheat 10 minutes;
 - 3, Add 30uL of blood plasma, warm up 3 minutes (sample will add to cup bottom, there can not be bubble) in advance;
 - 4, Put hot sample cup into test cannel, sample pipette absorb 30uL TT reagent;
 - 5, Press " OPTIC1~2", screen display "INPUT REAGENT ", join PT reagent, (must press all hearing sound), instrument begins test;
 - 6, About 40 seconds, screen shows " + + +. + S ";
 - 7, Repeat 5-6 step can test continuously. press " MENU ", return main menu.

TEST CODE	SAMPLE (uL)	REAGENT1(uL)	REAGENT2(uL)
PT	20	40	
APTT	20	20	CaCl ₂ 20
TT	30	30	

4 Blood sample and reagent Consumption frequently as flowing:

Second section Daily defend and maintain

Daily maintenance and maintenance divide as flowing:

- 1, Everyday maintenance: check optical cannel and each hot cannel whether do not have completely to touch dust every day, necessity with the soft paper of camera lens clean.
- 2, Instrument appearance washes: When washing instrument shell, can clean with wet cloth (must turn off power switch, pull out the socket of power source), can also use detergent, but must not use the organic solvents such as alcohol to wash.

Fault phenomenon	reason	Processing technique
	1. Power switch turn off	Turn on power switch
Screen not	2. Power source is obstructed	Insert the plug of power source again
display	3. Show line pine is taken off	Insert again to show cable
	4. Screen spoils	Connect maintenance engineer to change
		show screen
	1. IN-LINE lamp does not light	Press IN-LINE key, till lamp light
Printer not print	2. No print paper	Change print paper recently
	3. After tearing paper, print paper block	Cleaning blocks paper position
	4. Print paper surface to pack turn over	Install print paper again
Test result not	1. Reagent becomes invalid	use effective reagent
steady 2. Do not warm up reagent and sample		test according to working instruction
	strictly in advance according to working	
	instruction	
	3. Instrument fault	Connect maintenance engineer

Third section Common fault and handling

Appendix 1: English character input method

On instrument keyboard, key number is limited, so when input English character or symbol, it is multi-purpose a key to define for each digital key, introduce use method in detail as flowing: Each digital key and English character are as follows in correspondence with relation:

 1 ----- A, B, C
 2 ----- D, E, F
 3 ----- G, H, I

 4 ----- J, K, L
 5 ----- M, N, O
 6 ----- P, Q, R

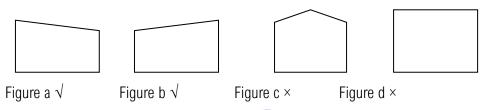
7 ----- S, T, U 8 ----- V, W, X 9 ----- Y, Z, _ 0 ----- --, _, /

Character size convert as flowing: Please use key "OPTIC", Do not press "OPTIC", screen display" A " in right corner, right now input is capital letters, after press "OPTIC" key one time, screen display " a " in right corner, right now input is the character of small letter, again press "OPTIC" input is again capital letters, depend on this cycle.

Appendix 2: Print paper installation method

Print paper to install step:

1. Print paper may be cut shown as figure a and b, the shape figured as figure c and figure d install relatively difficulty;



- 2. Press 'IN-LINE' key, in-line lamp turn off;
- 3. Press" FEED ", makes printing head revolve.
- 4. Put paper into paper mouth, when feeling paper is being voluntarily ongoing, stops making by hand;
- 5. When printing paper sending completely from paper end, press "IN-LINE " key, the printer is in waiting stage (if want printer can print, the in-line lamp must be light).