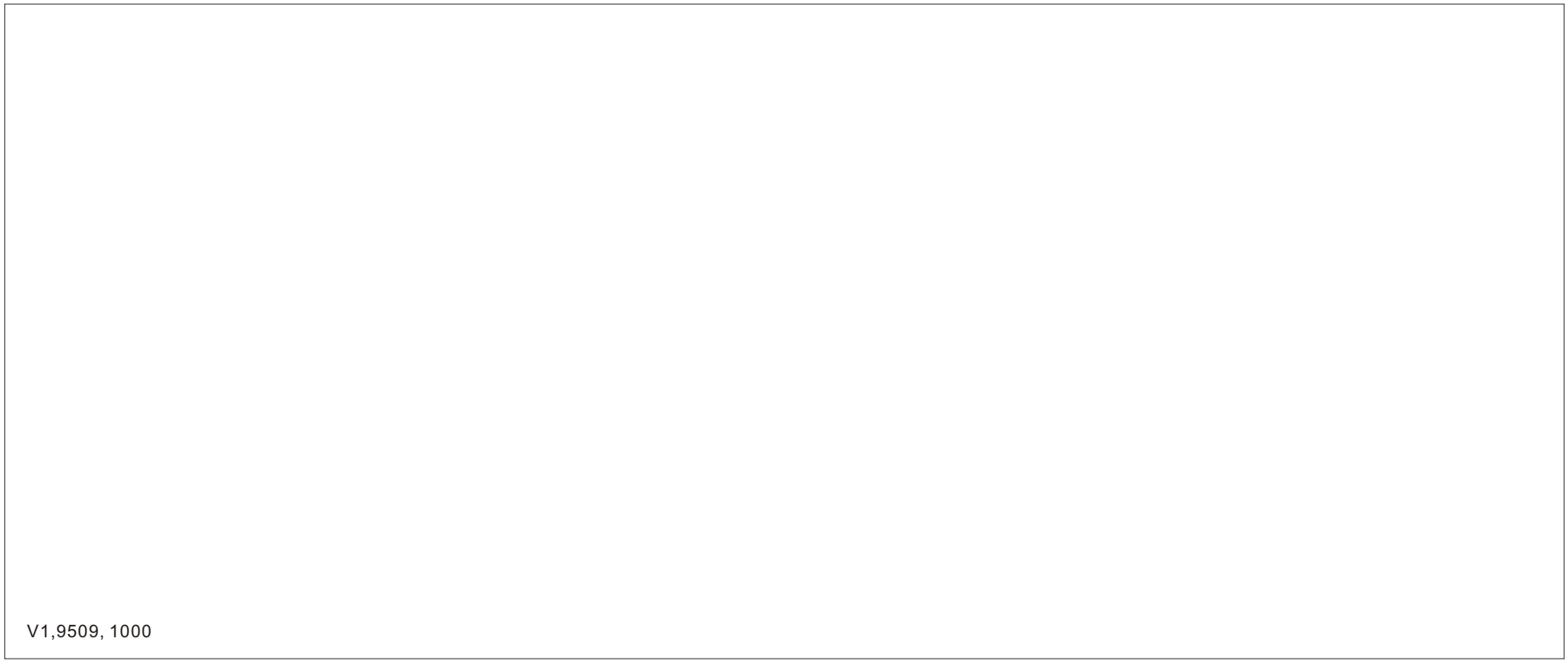
UNISCAN™ Scanner
User Guide


V1,9509, 1000

Notes:

Read all instructions first.

Check for and **be familiarized** with the kit before performing tests.

Please contact your authorized Suns Bio-Med representative if the kit is missing any of its contents.

The UNISCAN™ System

UNISCAN™ System = UNISCAN™ Scanner + UNISCAN™ Test Strip

The UNISCAN™ system is a multiple-use test system that can be used on-site in a variety of repetitive testing environments. The UNISCAN™ Scanner provides a convenient and portable tool that alleviates test performance dependence on the visual acuity and interpretive skills of the user.

What you need to know about using the UNISCAN™ system is included in this User Guide. If you have any questions, please feel free to contact your authorized Suns Bio-Med representative.

UNISCAN™ Test Strips

UNISCAN™ Test Strips are specially designed and extensively optimized for qualitative, semi-quantitative, and quantitative use with the UNISCAN™ Scanner.

Use only UNISCAN™ Test Strips to ensure consistent quality and reliable results, and to maintain our complete service, support and warranty.

CAUTION

Test Performance may be negatively impacted if the test is performed by users with less training, familiarity, or experience, who do not follow instructions, or use unapproved or non-UNISCAN™ accessories.

If the equipment is used in a manner not in accordance with its recommended or intended use, then the safety and effectiveness of the equipment may be impaired.

Sudden or extreme changes in environmental conditions - such as temperature, relative humidity, outdoors to indoors - will be detrimental to UNISCAN™ system performance and equipment.

Bleach will react negatively with UNISCAN™ Test Strips and cause false results. If a diluted bleach solution is used to disinfect the UNISCAN™ Scanner, then please be sure to wipe away completely any bleach from the Scanner with a cloth dampened with water.

IMPORTANT

Please read all instructions and practice the test before using the UNISCAN™ Scanner to perform (live) tests.

The UNISCAN™ system is intended for testing and/or screening purposes. It is not intended for diagnostic or confirmatory use.

Tests can be performed only with specified sample types, such as urine, and only with UNISCAN™ Test Strips.

Perform all quality control checks as directed.
[See Page 10].

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Symbols

Symbol	Used for
IVD	*In vitro* diagnostic medical device
EC REP	Authorized representative in the European Community
	Manufacturer

Symbol	Used for
	Date of manufacture
REF	Catalog number
LOT	Batch code

Symbol	Used for
SN	Serial number
	Consult instructions for use
	Caution, consult accompanying documents

Symbol	Used for
	Temperature limitation

Graphic symbols for use in labeling

Contents of kit

- UNISCAN™ Scanner
- AC Adaptor
- Calibration Strips
  -one **Bright** standard
  -one **Dark** standard
- User Guide

Conditions and Requirements (Terms of Use)

Shipping and Storage Ranges:

- Temperature: -20~60°C (-4~140°F)
- Relative Humidity: 10~85%RH

Operating Ranges:

- Temperature: 15~40°C (59~104°F)
- Relative Humidity: 30~85%RH
- Atmospheric Pressure: 700~1060hPa

Conditions and Requirements (Terms of Use)

Note: Recommended for use in a controlled environment

- Clean work area
- Room temperature
- Available power source
- Stable environmental conditions
  (e.g., Temperature, Relative Humidity)
- UNISCAN™ Test Strips
  Do not use non-UNISCAN™ Test Strips with the UNISCAN™ Scanner
- If necessary, dispose of the UNISCAN™ Scanner in an environmentally friendly way at the end of its lifetime; follow local regulations.

System Introduction

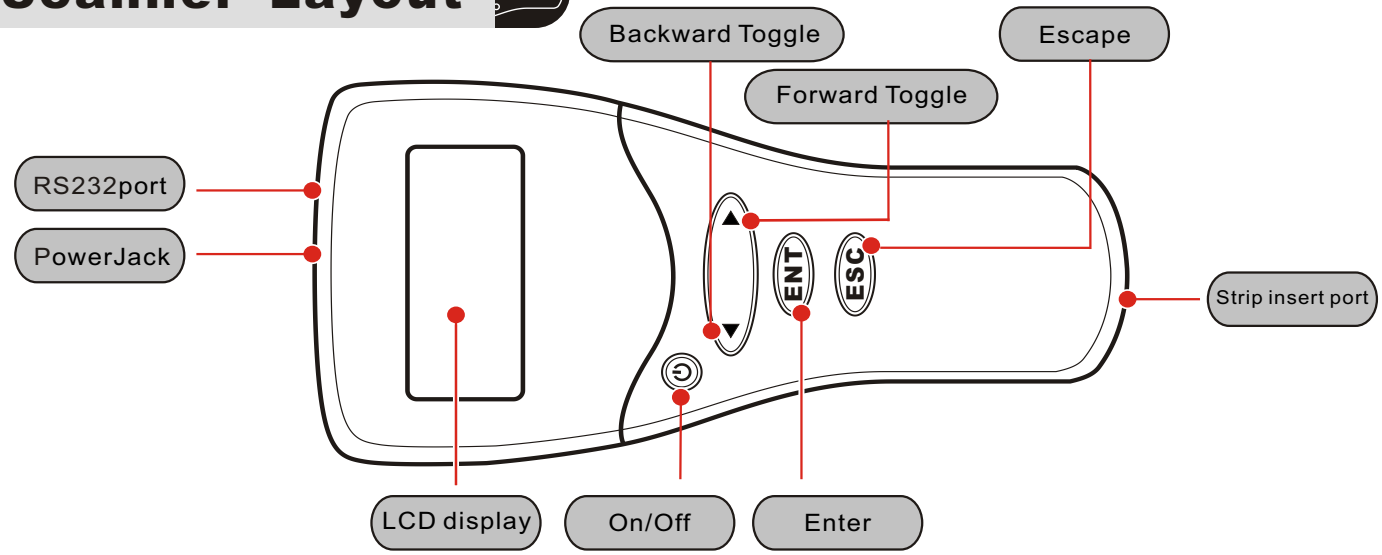
UNISCAN™ System = UNISCAN™ Scanner + UNISCAN™ Test Strip

The UNISCAN™ Scanner performs color signal analysis on a reacted immunodiagnostic UNISCAN™ Test Strip. Digital signal processing and a mechanical design enhance the system's measurement accuracy. The handheld Scanner is portable and provides an instrument-based analysis and record in seconds, thus reducing human error and guesswork in the test process.

Scanner Specification

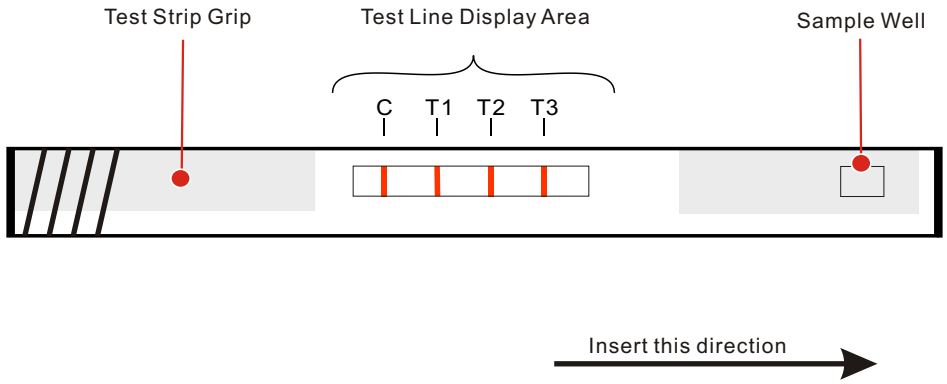
- Display: 16 x 4 Backlit LCD
- Test Analysis Functionality:
  -6 selectable control panels for different Test Strips
  -Each control panel can process up to 3 test analytes
- Testing Time: < 20 seconds
- Test Result Log Capacity: 135 sets of test results
- Data Interface: RS232
- Print Function: Supports RS232 Printer
- Power Supply: AC/DC Switching Adaptor ES18U09-P1J
  MEAN WELL Enterprises Co., Ltd.
  Input: 100~240V AC, 50/60Hz, 0.5A
  Output: 9V ⎓ 2A,18W Max.
- Dimensions (LxWxH): 20 x 10 x 3.5cm
- Weight: Approximately 280g

Scanner Layout



Test Strip Layout

[Sample Test Strip with 3 Test Lines*]



Legend	
C	Control Line
T1	Test Line 1
T2	Test Line 2
T3	Test Line 3

*The number of Test Lines varies for each Test Strip type.

Control Panel and Test Analyte Specs/Input/Guide

Six control panels are provided to correspond exactly with different types of UNISCAN™ Test Strips. Each control panel contains different settings so that the UNISCAN™ Scanner can accurately calculate the appropriate set of test values.
For instance, Test “X” requires the use of Panel 1 in order to calculate the test result value.

[Test Strip Calibration]

-The number of Test Lines is different for each Test Strip.
-The chemical composition of each Test Line is different for each analyte*.
-The calibration characteristics for each production lot of Test Strips will vary, so calibration data is necessarily established for each Test Line upon production.
-The user must set the "Panel No." correctly according to the Test Strip type, and then input the Strip Calibration Curve (i.e., “STD curve”) data. Only now will the analyte be evaluated properly.

*Analyte: item to be tested

Panel	Item			a, b of STD curve			Strip
1	X			a_{t1}, b_{t1}			C t1
2	Y			a_{t1}, b_{t1}			C t1
3	X	Y		a_{t1}, b_{t1}	a_{t2}, b_{t2}		C t1 t2
4	X	Z		a_{t1}, b_{t1}	a_{t2}, b_{t2}		C t1 t2
5	Y	Z		a_{t1}, b_{t1}	a_{t2}, b_{t2}		C t1 t2
6	X	Y	Z	a_{t1}, b_{t1}	a_{t2}, b_{t2}	a_{t3}, b_{t3}	C t1 t2 t3

Input the above parameters using the toggle button on the device.
[See Page 16 for step-by-step instructions]

TABLE (1) Examples of CONTROL PANEL AND TEST ITEM

Note: “X”, “Y”, and “Z” are used figuratively here to represent different types of test analytes.

Test Report Printout Format

The UNISCAN™ Scanner can connect with a printer via RS232 to print out a Test Result Report. The printout format may be similar to TABLE(2).

Legend	
Y	Year
M	Month
D	Day
H	Hour
M	Minute
SN	Serial Number*
PN	Panel Number
#	Wild card numerical value
+	Positive test result
-	Negative test result
*	Quantitative value

*Sequential Test Number

No	Format
1	yy/mm/dd hh:mm SN: ### PN: # X + ****
2	yy/mm/dd hh:mm SN: ### PN: # X + **** Y - ****
3	yy/mm/dd hh:mm SN: ### PN: # X + **** Y - **** Z + ****

TABLE (2) Examples of PRINT OUT FORMAT

Before You Use the Scanner for the 1st Time

1 Set the Clock

Please set the date and time before you start using your new UNISCAN™ Scanner.
Date and time are critical to accurate recording of results and record keeping.

2 "*Bright*" and "*Dark*" *standard* calibration

"***Bright***" and "***Dark***" ***standard*** calibration is critical to the UNISCAN™ Scanner's measurement consistency. [See Page 14 "Scanner Calibration"]

NOTE: Do not use the **"Bright"** and **"Dark"** ***standard*** calibration strips if they are discolored, scratched or dirty.

Calibration Schedule	**Monthly, or more frequently**
	Re-calibrate when operating temperature fluctuates in a wide range, e.g. ± 15°C.

Before You Start Testing with the Scanner

1 Check the STD Curve settings

Always check the settings of the Strip Calibration Curve against the Test Strip type. Adjust the STD curve settings accordingly. [See Page 7 for instructions]

2 Use the Control Solution

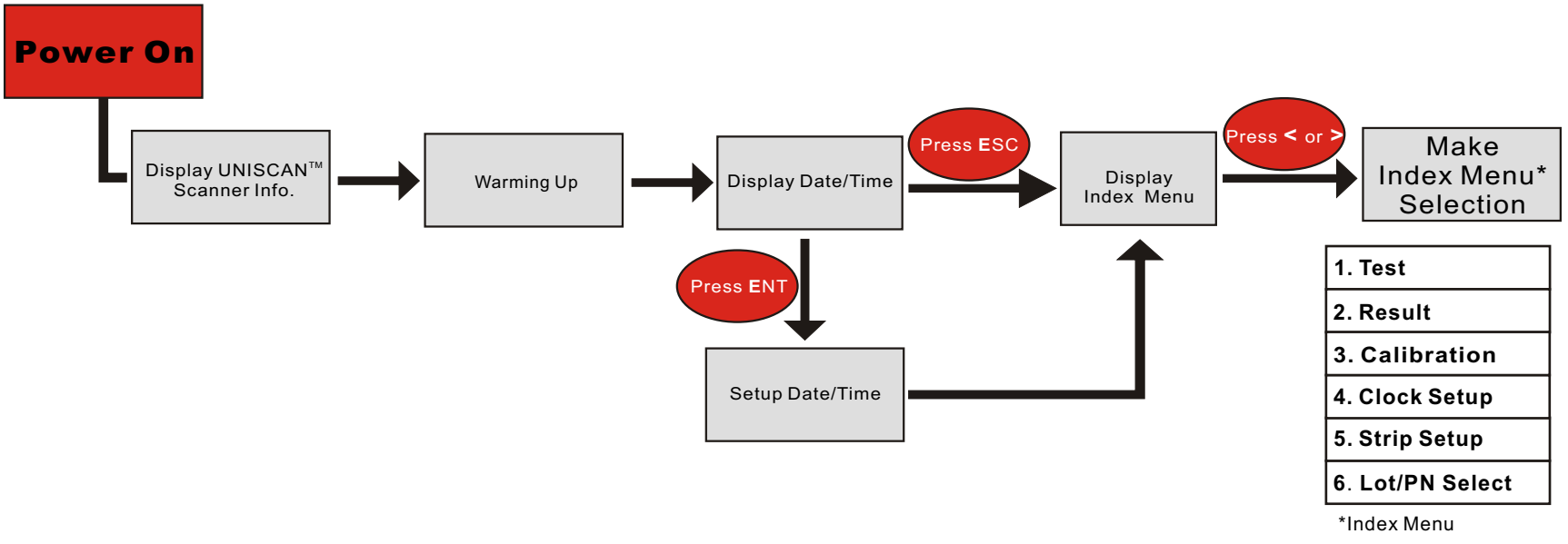
The Control Solution contains a known amount of Test Analyte. Use the Control Solution to check whether the Scanner and Test Strip are working together properly.

If you get a "False" result, do not proceed to use the Scanner to test samples.

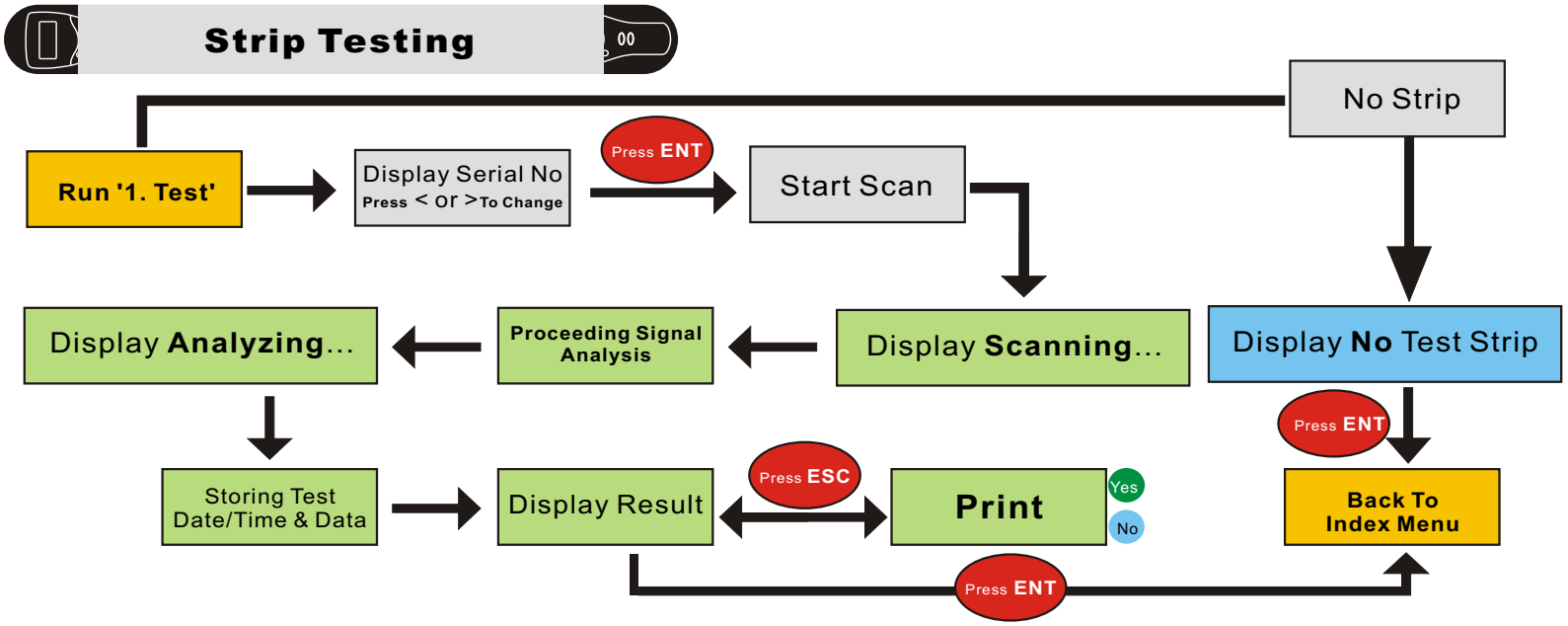
Contact your authorized Unison Biotech representative for more details.

Control Solution Schedule	**Monthly.**
	Check the system when using a new lot of Test Strips.

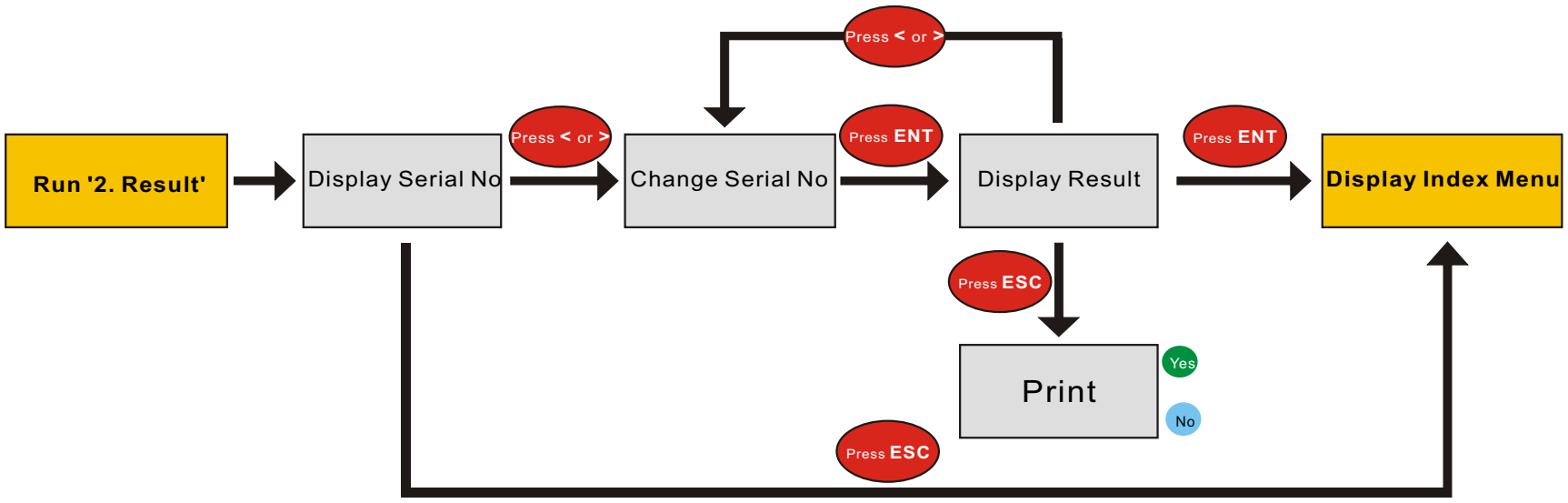
Power On/Selection Menu/Index



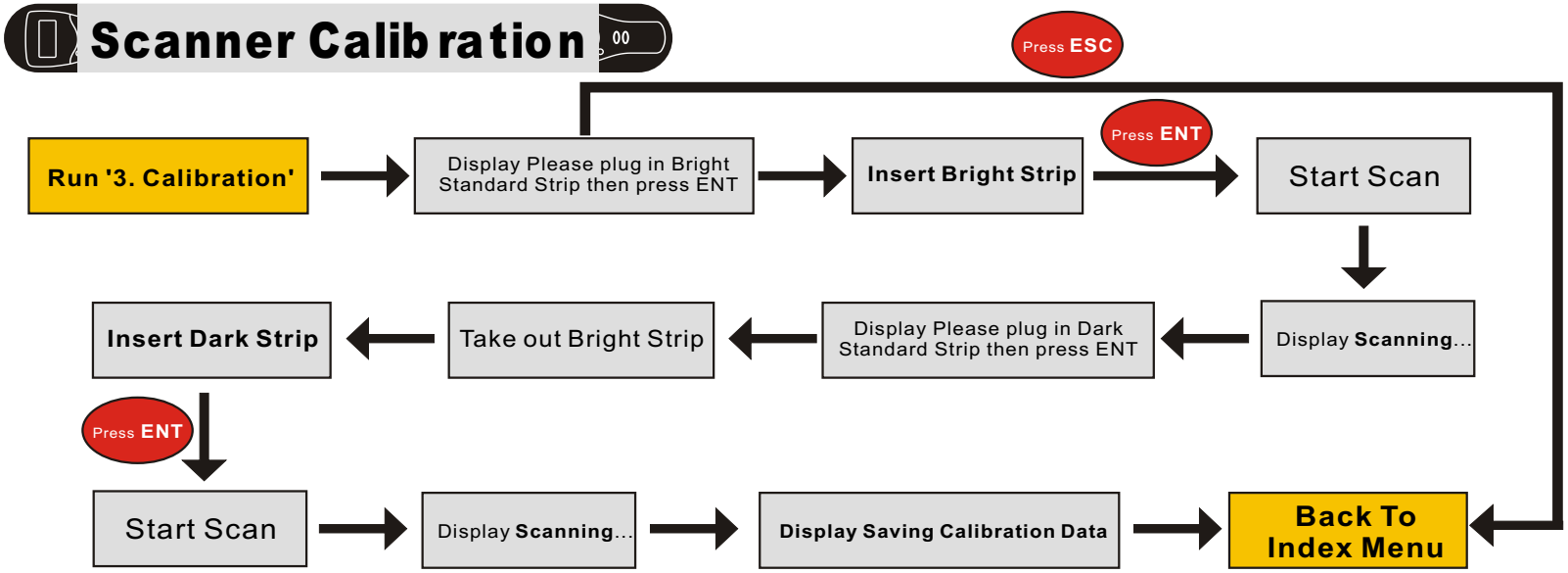
*Index Menu


Strip Testing
No Strip
Run '1. Test'
Display Serial No
Press < or >To Change
Press ENT
Start Scan
Display Analyzing...
Proceeding Signal Analysis
Display Scanning...
Display No Test Strip
Press ENT
Storing Test Date/Time & Data
Display Result
Press ESC
Print
Yes
No
Back To Index Menu
Press ENT

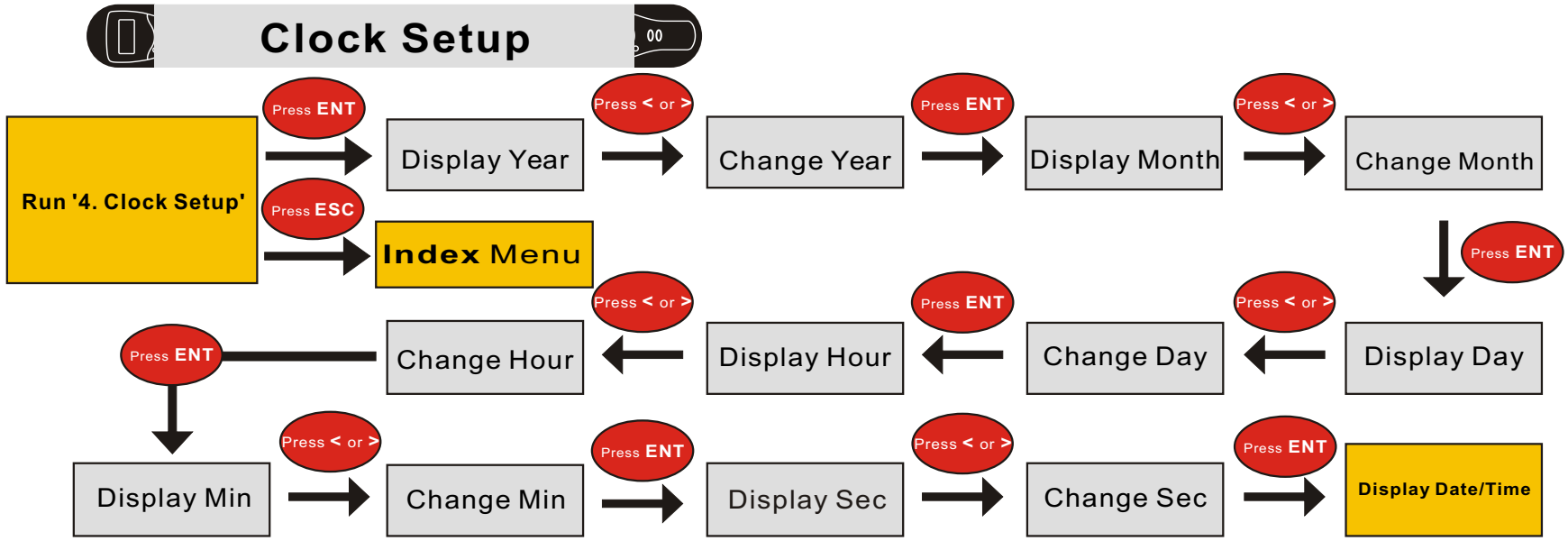
Test Record Inquiry

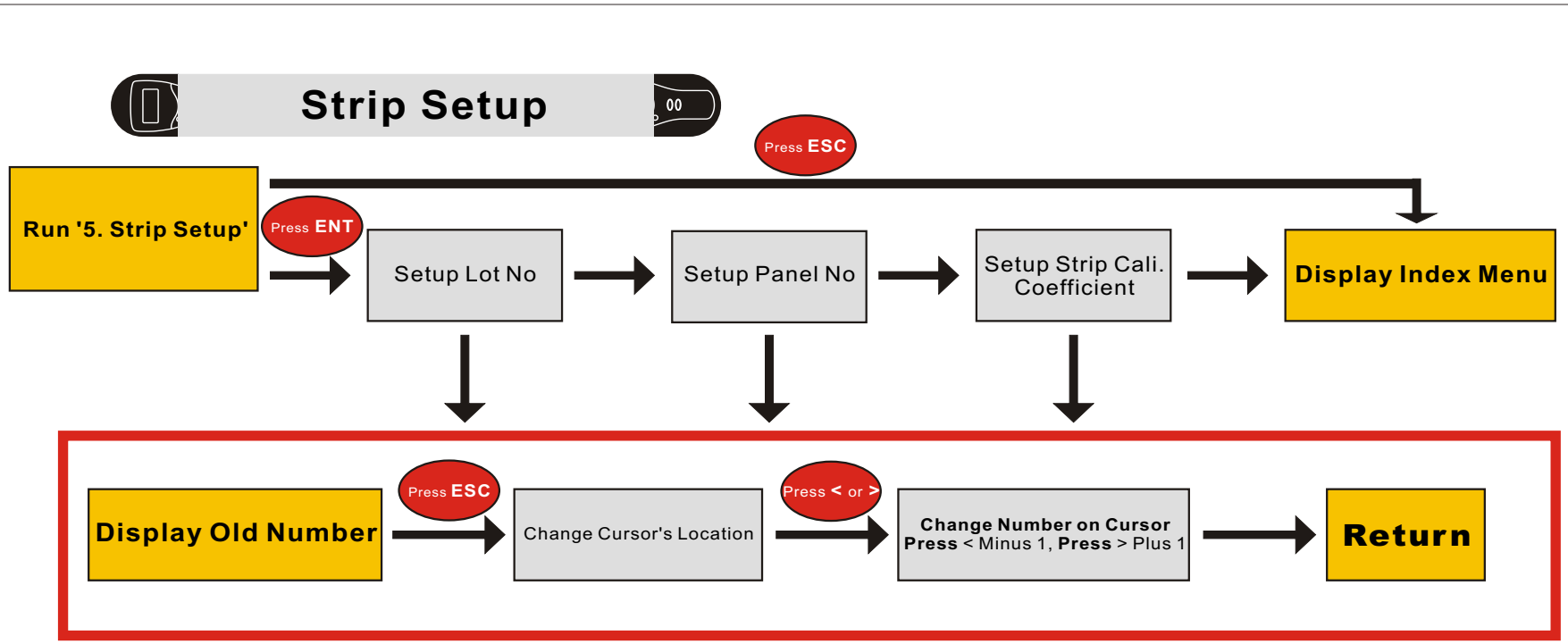


Scanner Calibration

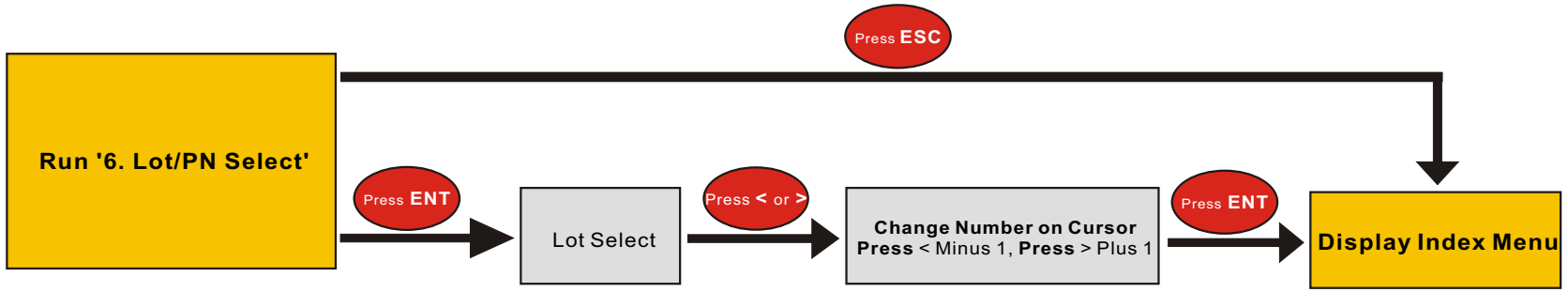


Warning: Do not use the **"Bright"** and **"Dark"** ***standard*** strips if they are discolored, scratched or dirty.
Keep them away from dust, dirt, and UV-filled light (sunlight).


Clock Setup
Run '4. Clock Setup'
Press ENT
Press ESC
Index Menu
Display Year
Press < or >
Change Year
Press ENT
Display Month
Press < or >
Change Month
Press ENT
Display Day
Press < or >
Change Day
Press ENT
Display Hour
Press < or >
Change Hour
Press ENT
Display Min
Press < or >
Change Min
Press ENT
Display Sec
Press < or >
Change Sec
Press ENT
Display Date/Time


Strip Setup
Press ESC
Run '5. Strip Setup'
Press ENT
Setup Lot No
Setup Panel No
Setup Strip Cali. Coefficient
Display Index Menu
Display Old Number
Press ESC
Change Cursor's Location
Press < or >
Change Number on Cursor
Press < Minus 1, Press > Plus 1
Return

Lot/PN Select



Understanding Results

Test Results may have different meanings and impacts according to local standards and laws. Consult the Chart Insert in your UNISCAN™ Test Strip package and local regulations to determine different indications.

Please see Page 8 (“Test Report Printout Format”) for sample Test Results and code definitions.

Note: Valid Test Results will exhibit a small variance upon repeated scans. This is normal and consistent with standard laboratory practices and analyzers as well.

Troubleshooting

“No Strip”	● Test Strip is not inserted.
“Strip is failed”	● Control line does not appear. Use a new Test Strip.
Scanner does not turn on	● Check for loose cables or connections. ● Check to see that the unit is plugged into a power source.
Inconsistent Test Results for the same Test Strip	● Re-calibrate Scanner. ● Check to make sure that the Strip Insert port is not subject to overexposure from external lighting. ● Test Strip is inserted too soon. Insert the Test Strip at the designated insertion time. ● Test Strip is inserted too late. Insert the Test Strip at the designated insertion time. Excessive incubation will yield invalid test results.

Scanner Maintenance

1 General Care

- Keep dry.
- Avoid extremes or sudden changes in temperature and/or humidity.
- Avoid physical impact or rough handling.
- Do not disassemble.

2 Cleaning

- Use water only to wipe clean the surface. Do not allow water inside.
- Do not use cleansers or glass cleaners containing ammonia.
- Use a 10% bleach solution to disinfect, and then use water to wipe clean the surface.

Warranty

Date of Purchase:

Serial Number:

Complete the UNISCAN™ Scanner registration material and submit it as soon as possible.

If, for any reason except obvious abuse, the UNISCAN™ Scanner does not work at any time during the first year after purchase, your authorized Suns Bio-Med International Corp representative will replace it with a new or equivalent unit free of charge.

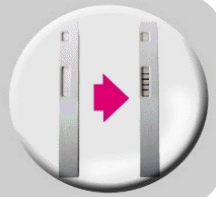
This Warranty Policy applies only to the UNISCAN™ Scanner and its original buyer.
It does not apply to UNISCAN™ Test Strips and disposable materials supplied with the UNISCAN™ Scanner.

This Warranty Policy is VOID if either the UNISCAN™ Scanner or UNISCAN™ Test Strips are modified or disassembled in any way without prior authorization. Only UNISCAN™ Test Strips can be used with the UNISCAN™ Scanner.

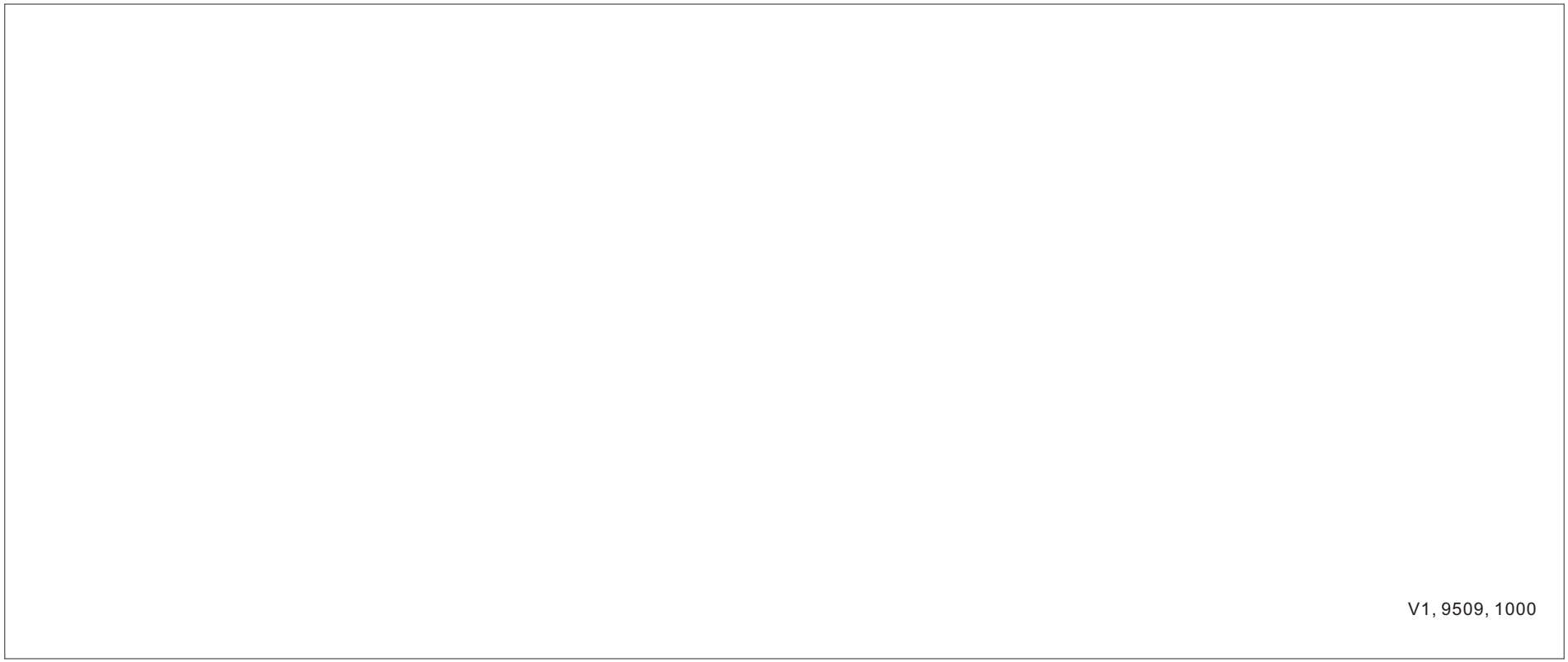
This Warranty is in lieu of all other warranties, express or implied, including any implied warranty or merchantability or fitness for a particular purpose.

Contact your authorized representative before you attempt to return your Scanner or any other products.

Quick Reference Guide

A. 	B. 	C. 	D. 
Add Sample Remove the Test Strip from the foil pouch and place it on a dry, flat surface. Add sample into the sample well.	**Process Test Strip** As the Test Strip begins processing,a color band will gradually appear across the Test Line Display area in the middle of the Test Strip.	**Wait, Insert** Wait and allow the Test Strip to mature for the designated incubation time. Insert into the UNISCAN™ Scanner. Use a timer if necessary.	**Read** Operate the UNISCAN™ Scanner to process and analyze the Test Strip. Interpret accordingly.Do not use test results when Incubation time exceeds the defined limit.

Caution: A. The designated incubation time is based on performing the test at room temperature.
B. If the test cartridge is functioning normally, then a control band will appear across the upper area of the window.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