

Blood Glucose Monitoring System Manual

Upgrade

115

182 15:31

Blood Glucose Monitoring System New bio-sensor technology : Fast & Accurate results in 9 seconds









Dear *finetest Auto-coding™* System Owner

Thank you for choosing the *finetest Auto-coding*TM Blood Glucose Monitoring System. This booklet has important information you must know about the *finetest Auto-coding*TM system. Please read it carefully.

We understand that self-testing of blood glucose level provides a way to control your diabetes and may give you peace of mind by testing regularly. As a result *finetest Auto-coding*TM was developed to provide you with a FAST and Accurate reading with a convenient and simple process. Our goal at *finetest Auto-coding*TM is to provide the best quality healthcare products coupled with superior customer service. Always consult with your healthcare professional before making any changes to your diabetes management. The *finetest Auto-coding*TM System is for in vitro diagnostic use only.

A warranty registration card is included with your system. Please complete the three year warranty card and send it to us. This will ensure that you receive any new information about your *finetest Auto-coding[™]* System. If you have any questions, please contact your local representative.

This is intended only for quick reference!

Before using the *finetest Auto-coding[™]* Blood Glucose Monitoring System, read all of the operating instructions in this Operation Manual.



Insert the *finetest Auto-coding*TM test strip. Code number is automatically displayed. Compare with code number printed on test strip vial. If not identical discard the test strip and restart.

Finctest Auto-Coding

Quick Reference



Collect blood sample





Apply blood sample until confirmation window is completely filled. Meter automatically begins to countdown. If the countdown does not start, do not add more blood to the test strip! Discard the test strip a restart testing.

Test results appear in 9 seconds.



The *finetest Auto-coding*[™] Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use only). It should be used only for testing blood glucose and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes.

Consult your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer.

Please pay close attention when handling blood. Improper procedures may cause serious hazards to your health.

The *finetest Auto-coding™* Blood Glucose Monitoring System contains small parts. Please keep your monitoring system out of reach of children

Finctest Autocoding ™ Table of contents

Contents

PAGE

1. Learning the System

finetest Auto-coding [™] Blood Glucose Monitoring System KIT Contents	8
finetest Auto-coding™ Blood Glucose Meter	9
finetest Auto-coding™ Blood Glucose Meter Display	10
finetest Auto-coding [™] Blood Glucose Test Strip	11
Important Finetest Auto-coding TM Test Strip Information	12
2. Before Testing	
Setting the Meter	13 - 15
Auto-Coding Function	16
Checking the System with the <i>finetest Auto-coding™</i>	
Control Solution	17
3. Testing Your Blood Glucose	

3. Testing Your Blood Glucose	
Testing Your Blood - Preparation	19
Testing Procedure	20 21 - 24
Test Strip Ejector Function	25
4. Reviewing Your Results	26 - 27
5. Deleting Test Results	28
6. finetest Auto-coding [™] Software	29
7. Taking Care of Your Blood Glucose Meter	
Cleaning Your Meter and Maintenance	30
Replacing the Batteries	31
8. Troubleshooting	32 - 35
9. Test Principle and Performance	36
10. Specifications	37
11. Conversion table mmol/L <> mg/dL	38
12. Warranty	39
13. Symbols Reference	40

Finctest Auto-Coding

Blood Glucose Monitoring System KIT Contents



- 1. *finetest Auto-coding™* Meter
- 2. *finetest Auto-coding™* Test strips
- 3. Lancing Device
- 4. Lancets
- 5. Operation Manual
- 6. Warranty Registration Card
- 7. Patient Logbook
- 8. Two 3V Li-CR2032 batteries
- 9. Carrying Case

Check your *finetest Auto-coding*ⁿ system to make sure that it is unopened prior to use and that it contains all of the complete parts shown above.

If either of these conditions is not met, please do not use it. Contact the place of purchase to receive a new one.



Finctest Auto-Coding







W	Before having a meal						
	After having a meal						
å	After taking drugs						
Å	After sports activity						
● <mark>= </mark>	Blood drop symbol for test						
888	Test result display						
	Low battery warning symbol						
c	Measurement with Control Solution						
YRDAY.MON	Temperature / Date						
mmol/Lmg/dL	Test result unit symbol						
AVR	Average displayed						
8888	Time						

*finetest Auto-coding*TM test strips are to be used with *finetest Auto-coding*TM and *finetest*TM meters only.

Finctest Auto-Coding

Test Strip

Opening of the measurement chamber Confirmation window



Storage and Handling Caution

- 1. Keep out of direct sunlight.
- 2. Store the *finetest Auto-coding™* Test Strip vials in a cool, dry place between 2-30°C. Do not refrigerate or freeze.
- 3. Make a notation of the discard date on the vial label when you first open it. Discard remaining *finetest Auto-coding™* Strips 3 months after first opening the vial.
- Close the vial cap tightly immediately after removing a *finetest Auto-coding™* test strip.
- 5. Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
- Avoid getting dirt, food or water on the test strip. Do not bend, cut, or alter the *finetest Auto-coding™* Strip.
- 7. *finetest Auto-coding™* test strips are for single use only.
- 8. Keep the test strip bottle away from children.
- 9. Please refer to the user's manual for *finetest Auto-coding™* blood glucose test strip for additional information.

The *finetest* Auto-codingTM has a variety of excellent functional modes and options:

Finetest Auto-Coding

Before Testing - Setting the Meter

Up to 5 alarms at planned testing times, unique User ID option, ability to designate activities related to the test result, and the ability to designate three different numbers of days for average calculation.









4. To turn the meter off during setup, press ① for at least 3 seconds

Finctest auccount ™ Automatic code recognition

1. *finetest Auto-coding*TM has automatic

2. It recognizes automatically the code

number. This is a very convenient

function preventing the inconvenience

of setting the code number on the

meter every time.

code recognition function.



Caution

- 1. Do not bend the test strip to prevent the Automatic code recognition failure.
- If the code recognition label is damaged, the code recognition may fail. Please check the code number on the LCD display window with the code number on the test strip vial.

Checking the system with the *finctest* measure control solution

Checking the system with the $\mathit{finetest}\,\mathit{Auto-coding^{\textsc{tm}}}$ control solution

The *finetest Auto-coding*TM Control Solution is used to check that the meter and the test strips are properly working together to provide you with the most accurate reading.

Note : The *finetest Auto-coding*TM Control Solution is sold separately. Low, normal and high level control solutions can be obtained through your local representative.

Control Solution Test can only be used with the *finetest Auto-coding*TM System and should be used during the following cases:

- When a new vial of test strips is opened.
- Any suspicion that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with your symptoms, or if you think they are not accurate.
- If you drop the meter.
- Use routinely to obtain accurate results.

When the control solution is applied to the top edge of the *finetest Auto-coding*TM Test Strip, you should get results within the expected range printed on the label of the test strip vial. If the control solution test results fall outside the range, repeat the test. Results that fall out-side the range may be caused by:

- Error in performing the test.
- Failure to shake the control solution vial well enough (must shake vigorously).
- Failure to discard the first drop of control solution.
- Expired or contaminated control solution.
- Test Strip deterioration.
- Meter malfunction.
- Control solution that is too warm or cool.

Checking the system with the *finctest* accessor control solution

Testing procedure

- 1. Prior to use, shake the bottle gently several times.
- 2. Invert bottle and discard the first drop of control solution.
- 3. Wipe the dispenser tip clean.
- 4. Test strip is inserted fully into the test slot of the *finetest Auto-coding*TM meter.
- 5. Be sure the code number appearing on the LCD window matches the test strip code on the strip vial.
- 7. Hold the control vial at an angle with the tip near the end of the test strip. Gently squeeze the vial and form a small drop. Pick up the meter and touch the end of the test strip to the hanging drop. Be sure to hold the test strip to the drop until the "beep" sounds.
- 8. After the "beep" sound, wipe the rest of the drop with tissue or cotton gauze.

If the drop is taken back into the control vial, it is possible to contaminate the whole vial of control solution!

9. The displayed test result should be within the range printed on the test strip vial.

Second application tip : Place a drop on clean aluminum foil, glass or plastic plate and touch the end of the test strip to that drop. This method is more favorable, in preventing contamination to the whole vial of control solution

IMPORTANT NOTE : If the *finetest Auto-coding*TM Control Solution test results, continuously, falls outside the range printed on the vial, the *finetest Auto-coding*TM system may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result that falls within the range. If you continue to have problems, call your Customer Support and Service.

In the User ID option is activated, the control solution test result is stored, but can only be recalled after deactivating the User ID option.

Before testing, be sure to read this section and test strip package insert found in the test strip box carefully. Make sure you have all the necessary items to begin the test:



finetest Auto-coding™ Meter
finetest Auto-coding™ Test Strip
Lancing Device
Sterile lancets

-finctest Auto-Coding

Testing Your Blood - Preparation

Caution

To reduce risk of infection :

- 1. The lancing device and sterile lancets should NOT be shared with others.
- 2. Always use a new, sterile lancet and a new strip
- 3. Practice using the Lancing Device and become accustomed with its use.
- 4. Lancets and strips are for single use only.
- 4. Wash your hands with warm, clean water and soap before testing.
- Avoid getting hand lotion, oils, dirt or debris on the lancets or on the lancing device.
- 6. Dry your hands completely before testing.



Testing Your Blood - Collecting a Drop of Blood



-finctest Auto-coding

1. Unscrew the lancing device tip and insert a lancet firmly into the carrier.



2. Pinch the lancet and twist off the protective cover. Re-screw the tip on the lancing device.

3. The tip of the lancing device offers 5

different levels of skin penetration. To

select the best depth: Use 1-2 for soft or

thin skin, 3 for average skin, 4-5 for thick

4. Hold the tip in one hand and pull on the

sliding barrel with other hand. Pull the ends apart and you will feel a click. This

indicates that the lancing device is in a

locked position ready for lancing.

or calloused skin.







5. Release the sleeve. It will automatically contract and move back to it's original position near the trigger hub.



 Place the lancing device against the tip of the finger. Press the trigger button. Your blood sample should now be ready to be applied on the test strip. Lift the lancing device out and away.

Step 1

180 8888

Firmly insert the *finetest Auto-coding*TM test strip into *finetest Auto-coding*TM Meter test port. Insert down firmly in direction of arrow on test strip (arrow up). Please do not insert the test strip upside down. When you insert the test strip into the meter, the power automatically turns on with the code and temperature. After 3 seconds, the code number and testing temperature will disappear. When the strip sign blinks, apply your blood to the test port of strip.

NON YAD NON YAD

Note : Inserting the test strip in the wrong direction will turn the meter on, but you will be unable to test.

Caution

- 1. If the code is not displayed after 3 seconds, pull the test strip out of the port, and re-start the procedure from the beginning.
- If the code on the LCD display window and on the test vial does not match, try another new strip. If the mismatch persists, please contact your local representative for help.
- 3. If the meter does not power on, pull the test strip out of the port, and re-insert the test strip.
- 4. Avoid testing under direct sunlight, for a more accurate test result.
- 5. If you apply your blood sample too early, ERROR5 message will appear on LCD (refer to p33).



Correct : Completely filled





correct

Incorrect : Poorly filled





incorrect

Step 2

Place your fingertip to the top edge of *finetest Auto-coding*TM Test Strip. The blood on your finger will automatically draw into the applying channel of the test strip. Allow your finger to remain until you hear a "beep" sound from the *finetest Auto-coding*TM Meter. A sample volume of 1.5µl is required.

Caution

- 1. If the countdown does not start, do not add more blood to the test strip! Discard the test strip an restart testing.
- If you do not conduct the test within 3 minutes, the meter will automatically power off to save battery life. In this case the test procedure should start again from the beginning.

Finctest Autocoding™ Testing Procedure



Step 3

After the beeping sound, the test will begin automatically and your results will appear in 9 seconds. It should begin counting down from 9 to 1 second on the LCD display window. The LCD window will display the result of your blood glucose level, temperature and time.



Record the result value in your logbook. When test strip is removed, the meter turns off automatically.



Caution

- 1. If the test result is out of the test range, the Hi/Lo message will be shown on the LCD. (refer to p34)
- Safely discard used test strip and lancet, to a proper place, according to the local regulation.



Testing Your Blood - Case of activated User Activity option and User ID option



Step 4-1

If you selected to use the User Activity option during set up, press up and down button to select the activity that correlates with your result (refer to p10), then press \mathbf{O} .

If you do not select to use user activity option during set up, press \bigcirc to continue to step 4-2.

Step 4-2

If you selected to use the User ID option during setup, press \blacktriangle and \checkmark button to select the correct User ID, then press \bigcirc .

caution

- 1. If you did not activate the User Activity option and/or the User ID option, Step 4-1 and/or Step 4-2 procedures are not conducted.
- Although User Activity option and/or User ID option are activated, if you pull the test strip out right after the test, you can not move onto step 4. The test result is stored, not under a specific User ID and only displayed after deactivating the User Id option.
- Please refer to page 13, if you want to set the User Activity option and User ID option.



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Test strip ejector function

- 1. After checking your test result, slide the ejector button twice forward to remove the test strip from the meter.
- 2. Discard the used strip and lancet to a proper place, according to the local regulation.

Caution

- 1. If you push the ejector button forward too much, it may be damaged.
- 2. Do not give strong impact to meter.



The *finetest Auto-coding™* saves up to 200 test results in its built-in memory and records the average glucose level for the number of days which you had preset to be calculated and saved. These values can be recalled in the LCD display at any time. The newest result will replace the oldest beyond the 200 data stored.

Press () shortly

If the User ID option has been disabled during setup the newest data will appear immediately.

You can check your individual data of the latest 3 days and average over previously set up 3 different numbers of average days through pressing \blacktriangle/∇ button.

Ex>



Press down button: displaying the previous result Press up button: displaying the 7d \rightarrow 14d \rightarrow 21d average test result



Reviewing your results with activated user ID



Pressing the ① button once and the User ID option will appear in the LCD screen.



After entering the user ID mode, use \blacktriangle and \blacktriangledown button to scroll and choose the correct user ID, then press the O button.



* If you choose the User ID to check the stored results, only the results of the selected user are displayed.



*finetest Auto-coding*TM has the deletion function.



deleting individual test result

To delete any individual test result in the memory press \blacktriangle or \checkmark button for 3 seconds, while the test result to delete is displayed. dE_{\perp} is blinking. After the second beep sound the test result is deleted.

Blood Glucose Program

Finctest Auto-Coding

You can transfer test results from the *finetest Auto-coding*TM meter to a computer where the data can be further analyzed.

You can download for free the *finetest Auto-coding™* Blood Glucose Program at our web site http://www.infopia21.com

You can purchase the communication cable separately from a local representative.



deleting all test results

To delete all test results press \blacktriangle and \blacktriangledown button at the same time for 3 seconds, while any test result is displayed. *d***EL** is blinking. After the third beep sound all test results are deleted.





- 1. Only selected Individual test results are deleted when you recalled test results in the user ID condition
- 2. The deleted test results can't be recovered. Please be careful in deleting the test results.

6

Finctcst Autocoding ™ Replacing the batteries

Finctest AutocompTM Taking care of your glucose meter

Cleaning your meter and maintenance

For safe, accurate and long-lasting use of the *finetest Auto-coding*TM Meter, the meter must be maintained with proper cares

- 1. The meter should be cared for after testing and cleaned if necessary with a soft cloth or tissue. If necessary, rubbing alcohol can be used to wipe away dirt on the outer surface of the meter. Do not use chemical solutions such as benzol or acetone since both of these solutions can harm and damage the meter surface. When cleansing the meter with rubbing alcohol, DO NOT pour directly onto the meter, but use the cloth soaked with a small amount of alcohol. After cleansing the meter, dry completely at a cool place avoiding the sun rays.
- 2. Do not soak the meter and test strip into water or liquid. Use as properly as you can. Strong electromagnetic fields (e.g. mobile phones, microwave ovens) could disturb the meter function. Do not put the meter and strip near fire or microwave ovens.
- 3. After testing, place the *finetest Auto-coding™* Meter in the carrying case to prevent loss or damage. Make sure it is placed in a cool and dry area and out of the reach of children. Do not refrigerate. Avoid exposure to sun.
- Close the vial cap tightly immediately after removing a *finetest Auto-coding*[™] strip. Please refer to your *finetest Auto-coding*[™] strip instruction if you want to get more information.
- 5. The lancing device should be cleaned if blood or stain remains after to prevent infectious diseases.
- 6. When you need to purchase the lancing device, the lancets and test strip visit your local pharmacy or contact your local representative.
- 7. Discard used materials according to the local regulations for contaminated materials.
- 8. The blood glucose measuring meter could be sent back to the manufacturer for recycling or proper disposal after their useful lives. Alternatively the meter shall be disposed in accordance with national laws after their useful lives.
- 9. If *finetest Auto-codingTM* meter is not working properly, clean photo sensor with alcohol gauze after opening the ejector cover. Opening the photo sensor cover may affect the sensor performance, for which it is strongly recommended not to do open the cover for other purposes than cleaning

The battery shortage mark will appear in the middle left part of the LCD screen to alert you when the battery power is running low, indicating a new battery is needed. The *finetest Auto-coding*TM meter will not power on when the battery power is exhausted.

Your *finetest Auto-coding*TM meter uses two 3V Lithium battery (CR2032). The batteries are included in the set box. When replacing the batteries, only CR2032 or equivalent lithium batteries can be used.

Before replacing the batteries, make sure your meter is in the "OFF" position for meter safety. When changing your batteries, match the polarity symbols (+ or -) printed on the battery deck of the meter to the symbols on the face of the battery.



The following chart may help you identify certain problems, but may not solve all problems that can occur. Contact your authorized representative or customer support if the problem persists.





Problem with the Autocoding Label Please insert a new Blood Glucose Test Strip and perform your test again. If Er3 message persists, please contact your authorized representative or customer support.



603

DAY MON 19. 100805 The blood sample was applied before the (blood insertion picture) symbol appeared on the display (refer p21).

Repeat the test with new test strip. Apply blood only after the (blood insertion picture) symbol appears on the display.



The ambient temperature is too low

Place the meter within the operating temperature range for more than 10 minutes and retest.



What to do

Insert a new test strip. If Er4 message persists, please contact

your authorized representative or

customer support.





Message	Caused by	What to do	Problem	Caused by	What to do
X ([1 555	The ambient temperature is too High	Place the meter within the operating temperature range for more than 10 minutes and retest.	The meter does not power on	Batteries are dead or there is a problem with the meter	Change the battery and if the problem persist, contact you local representative.
LO DAY.MON 15 1 1 12:2 1	The test result is lower than 10 mg/dl (0.6 mmol/L)	Check the accuracy of your test strip by performing a control solution test. After, re-test with blood sample two or three times. When "Lo" message persists, please consult a doctor for assistance.	Test does not start after applying blood sample	Poor amount of blood sample	Please insert a new test strip and perform your test again applying sufficient amount o blood sample.
H I DAY.MON 15 1 1 122 1	The test result is higher than 600mg/dl (33.3 mmol/L)	Check the accuracy of your test strip by performing a control solution test. After, re-test with blood sample two or three times. When "HI" message persists, please consult a doctor for assistance.	The result is inconsistent	There may be a problem with the test strip Coding failure	Please insert a new test strip and perform your test again. Confirm that the code on the meter matches with the code or the test strip vial. If the code does not match, contact your local representative.

Finctest Autocours[™] Test Principle and Performance

Finctest Autocoding ™ Technical Specification

Measurement Range :

The measurement range of the *finetest Auto-coding*^m systems is 10 to 600 mg/dL (0.6 - 33.3 mmol/L).

Test Principle :

Glucose in the blood sample will react to the electrodes in the test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the *finetest Auto-coding*TM Meter and displayed as your blood glucose result.

Note: Different levels of reactions will occur depending on the amount of glucose in the blood sample.

Calibration :

The *finetest Auto-coding*TM system is plasma-calibrated to allow easy comparison of results with laboratory methods.

Accuracy :

Studies have shown that the test results of *finetest Auto-coding*TM systems compare well with laboratory methods.

Precision :

The precision of *finetest Auto-coding™* System has been assessed by studies in accordance with ISO 15197.

Results for venous blood samples and Control solutions :

Within Run Precision	Blood ¢	43 mg/dL	2,39 mmol/L	SD = 1.4	CV = 3.4%
	Blood ¢	91 mg/dL	5,05 mmol/L	SD = 2.2	CV = 2.4%
	Blood ¢	145 mg/dL	8,05 mmol/L	SD = 4.2	CV = 2.9%
	Blood ¢	223 mg/dL	12,38 mmol/L	SD = 7.7	CV = 3.4%
	Blood ¢	360 mg/dL	19,98 mmol/L	SD = 6.4	CV = 1.8%
Total Precision	Control∮	41 mg/dL	2,28 mmol/L	SD = 1.5	CV = 3.8 %
	Control∮	113 mg/dL	6,27 mmol/L	SD = 3.0	CV = 2.7 %
	Control∮	328 mg/dL	18,20 mmol/L	SD = 9.3	CV = 2.9 %

Sample type	Capillary whole blood
Sample volume	1.5µl
Test Range	10-600 mg/dL (0.6-33.3mmol/L)
Reading time	9 seconds
Calibration	Plasma - Equivalent
Operating Temperature	10-40 °C (50-104°F)
Operating Humidity	10-90%
Strip storage temperature	2-30 °C (35.6-86°F)
Display Type	LCD
Dimension	77 x 46 x 19 mm
Weight	42g (including battery)
Power source	3 V Li Battery (CR2032) x 2
Battery Life	Running 5,000 tests
Memory Capacity	200 test results
PC communications port	Communication is available to connect computer with cable

Finctest Auto-Coding

Conversion table mmol/L <-> mg/dL

mmol/L	0,55	1,0	1,5	2,(0 2,	22	,5	2,8	3,0
mg/dL	10	18	27	36	6 40) 4	5	50	54
mmol/L	3,3	3,9	4,0	4,4	4 4,	75	,0	5,5	6,0
mg/dL	60	70	72	80) 8	59	0	100	108
mmol/L	6,1	6,7	7,0	7,2	27,	57	,8	8,0	8,3
mg/dL	110	120	126	13	0 13	5 14	40	145	150
mmol/L	8,9	9,0	9,4	10,0	10,5	11,0	11,1	12,0	12,5
mg/dL	160	162	170	180	190	196	200	216	225
mmol/L	13,9	14,4	15,0	16,0	16,6	17,0	18,0	19,0	20,0
mg/dL	250	260	270	288	300	306	325	342	360
mmol/L	20,8	22,2	23,0	24,0	25,0	26,4	27,7	30,0	33,3
mg/dL	375	400	414	432	450	475	500	540	600



Three - Year Warranty

If, at any time during the first three years after purchasem the meter does not work for any reason with the exception of obvious abuse, misuse, or disastrous damage, infopia Co.,Ltd. will replace your *finetest Auto-coding*TM, Meter or equivalence free of charge.

The Warranty Policy of infopia Co.,Ltd. only applies to the original purchaser of the Meter and will not include the batteries supplied with the Meter set.

Please fill in the warranty card attached to the set. Mail or fax it back to us.

The *finetest Auto-coding*TM, Meter has a full three-year warranty from the original date of your purchase. For your convenience, please include your date and place of purchase.

Finctest Autocomer[™] Symbols Reference



Symbol i В **C**€0123 IVD \triangle LOT REF 1 8 \sim SELF-TESTING

Description

consult operating instructions

Expiry date

This prodect fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices

In-Vitro-Diagnosticum

Caution, consult accompanying documents

Batch code

Refrence number

Store at

Do not re-use

Use within 3 months apter first opening

Date of Manufacture

Self-testing Used

Waste electrical and electorinic equipment

Keep away from sunlight

Finctest Auto-Coding Memo



Manufacturer : infopia Co., Ltd.

891, Hogye-Dong, Dongan-Gu, Anyang, Kyunggi, 431-080, Korea

CE 0123

E

E 0434

Lancing Device Manufacturer :

Wuxi Xinda Medical Device Co.,Ltd. No.42 Xixin Road, Xibei Town, Wuxi, Jiangsu, China -----

Lancet Manufacturer :

SAE HAN Medical Corp. #700-113, Pugot-Dong, Ilsan-Gu, Goyang-City, Kyunggi-Do, Korea

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