



NiTek International Inc.

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WELCOME PACKAGE

Welcome to your new Thyrodine™ machine. Included in your package are:

1. **Hardware:** The Thyrodine dedicated laptop with the Thyrodine QFA 300 software, electrical cords, ADCM, Flow Cell, Valve Assembly, Sensor Harness, AC Power Adapter, USB Cable
2. **Supplies:** 3 Starter (3cc) Syringes, 2 starter (12 cc) Syringes, Waste Disposal Container, Drain Tube
3. **Solutions:** 500ml Cleaning Solution, 1 PPM Calibration Solution, 100 PPM Calibration Solution
4. **Supplies & Brochure Order Form**
5. **Troubleshooting & Technical Support**

Note: If you already have the Thyroflex, the same laptop can be used to run the Thyrodine test. Follow the software installation procedure to install the software. Additional literature and information on the device can be found on our web link <http://www.nitekmedical.com/thyrodine.html>



Thank you for choosing to become one of our select **Thyrodine** research group members. We will be contacting you in the near future to download your data for the research database (under the usual rules that apply to patient confidentiality). Thank you for your support.

Dr. Daryl Turner, CEO

Dr. Konrad Kail, COO





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THYRODINE™ INTRODUCTION

The Thyrodine Technology

The Thyrodine Iodide Quantitative Fluid Analyzer is an instrument that precisely measures iodide concentrations in body fluids. The laboratory measurement can be used to measure iodine in body fluids for many physiological purposes and has significance depending on the application. The analyzer will very accurately report these parameters:

- Iodine in saliva as an indirect measurement of the interstitial iodine concentration level.
- Iodine in whole blood as an indirect measurement of the sodium/iodine symporter efficiency.
- Iodine in urine as an indicator of the body's iodine sufficiency

Integrating the Thyrodine into your Practice

Integrating the Thyrodine into your practice is as easy as making copies of the Symptom Survey Sheet (provided in your welcome package) and having all patients who come into your practice fill out this quick survey while they are in the waiting room. Patient scoring 8 or above on their symptom survey has high risk of thyroid dysfunction and this is a good basis to test them on the Thyrodine.

Thyroid & Adrenal Research Institute (TARI)

Great information on the thyroid and adrenal can be obtained from the Thyroid & Adrenal Research Institute (TARI). Please visit their website www.thyroidinstitute.org. They provide special seminars, training programs and workshop to the healthcare professionals and the general public.

For Need Foundation

We support the "For Need Foundation", a not for profit 501.C.3 organization supplying much needed doctors and teacher for the poor in the Pacific Islands. Please visit their website www.forneed.org for more information and to make a donation.



THYRODINE™ OPERATING INSTRUCTIONS MANUAL

Software Installation

Perform the software installation before connecting the Thyrodine device to the computer's USB port. The Thyrodine Command Tool is supported on Windows 2000 and Windows XP.

1. Insert the Thyrodine CD and run "Install.bat". This program will create all the necessary directories and install all the files and drivers necessary to run the Thyrodine Command Tool. When the USB driver is installed, you may see a warning that the driver is not certified. This warning may be safely ignored. It may appear again if the New Hardware Wizard activates when a Thyrodine device is first connected to your PC. If the New Hardware Wizard activates, follow its instructions and allow it to complete installing the USB driver.
2. Connect the Thyrodine device to the computer's USB port, apply power to the Thyrodine device and then activate Thyrodine.exe. The installation program should have placed an icon labeled "Thyrodine.exe" on the computer desktop. If for some reason it did not, Thyrodine.exe may be found in c:\Thyrodine. Thyrodine.exe may be executed from this location or a shortcut can be created and placed on the desktop or any convenient location.

If the Thyrodine Command Tool fails to connect to the Thyrodine device it may be necessary to re-boot the computer for the driver installation to complete correctly. Disconnect the USB connection, re-boot, and re-connect the Thyrodine device to the USB port. If the New Hardware Wizard activates, follow its instructions, and then execute Thyrodine.exe.

Software Installation Troubleshooting

1. If the Hardware Wizard reports that the driver is not properly installed it may be necessary to re-run "Install.bat". Before doing so, delete the directory c:\program files\HSP and all its subdirectories and files. Install.bat will replace these files. If they are already present, Install.bat will report errors and fail to complete.
2. If the Thyrodine Command Tool reports "Unable to Open COMx" the USB port is not connected or the Thyrodine device power is not on or the driver is not enabled.
3. If the Thyrodine Command Tool reports "Data receive timeout" "Version not received" the USB connection is working properly, but the Thyrodine device is not



responding. This is probably a fault in the Thyrodine device. Try disconnecting and reconnecting power.

4. If the Thyrodine Command Tool reports anything to do with certificates not being present or valid, this is a network issue and is not related to the USB connection.

Instrument Set-up

1. Remove all components of the Thyrodine machine from the box.
2. **Install the Sensor into the Flow Cell**
 The sensor is shipped with a grey plastic caps (boot) on the ends. Please save these caps for future storage or your sensor. Avoid handling the glass ends of sensors. Use water to moisture the ends before inserting these sensors to create a better seal for the O-rings. Install the sensor to the back of the Flow Cell.



ADCM with Flow Cell



Sensor & Harness



Install the Sensor to Flow Cell

3. **Connect Sensor Harness to the Sensor & ADCM**
 Line up the notches on the sensor and harness before sliding the locking nut on. Slide the locking black boot over the exposed pins and turn to secure. Connect male end of the sensor harness to first female connect from the left found on the back of the ADCM. Insert, push in and turn right until the connection is snug. To remove, push in and turn left.



Connect Sensor Harness to Sensor



Connect Sensor Harness to ADCM

4. **Connect the Valve Assembly & Drain Line to Waste Disposal Container**
 Line the metal port of the Valve Assembly to the side of the Flow Cell. Push in and turn right to connect. Next, connect the drain line (found inside the waste disposal container) to the Flow Cell and connect the other end into the top of the waste disposal container.



Valve Assemble to Flow Cell



Drain Line found inside



Waste Disposal Container

5. **Valve Assembly Position Tip**

- Valve in the **UP** position, insert fluid (calibration solution, validation solution, saliva, urine, water) into the flow cell.
- Valve in the **HORIZONTAL** position, flush fluid out of the flow cell. Fluid will come over the top of the flow cell's stainless steel overflow chamber.
- Valve in the **DOWN** position, flush and dry the valve assembly using a syringe full of distilled water and syringe full of air.

6. **Connect the AC Power Adapter & Serial Cable to the ADCM**

Connect the AC Power adapter to the ADCM into the middle bottom output plug. Connect the bigger end of the serial cable to the left bottom panel and the USB end of the serial cable to the computer.



Connect AC Power Adapter to ADCM



Connect Serial Cable to ADCM

It is recommended that the AC Power Adapter is plugged into a surge protector.

7. Connect the laptop to the Internet

Internet connection is necessary in order for your system to do data analysis and to automatically download more tests from our server. Please contact your IT or service provider for instructions on setting up your Internet connection. NiTek can not provide assistant for the set-up of the Internet connection to the laptop.

Note: Do not load any other software on this computer. This is a precision medical screening device. The computer can only be used for the testing with NiTek medical equipment. If other software is loaded onto the machine, it will interfere with the testing result as well as the speed and performance of the computer.

8. Configure your Thyrodine Software for your Clinic

Launch program from desktop icon. Select "Setup" to enter your clinic information. All information entered now will appear on all your patient report. Click close to save the entries.

Calibration Preparation

The calibration of your instrument is the most important step you will take each day to assure accurate and precise readings. You must run a calibration every morning before you begin testing. The more frequently you calibrate or at least check your calibration through validation, the greater the accuracy of the analysis.

Helpful Tips:

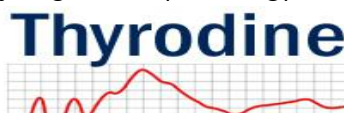
- Never pour any unused calibration solution back into the original bottle.
- Always keep the fresh calibration solutions sealed tightly and stored away from extreme temperature changes and direct sunlight.
- Always check to see that the syringes and beakers that are used for calibration are clean, dry and free from outside contamination.
- Inject fluid slowly into the flow cell helps eliminate air bubbles, a common cause of error messages and faulty readings.

1. Pour a small amount of buffer solution into a glass beaker.

2. Pour distilled water into another glass beaker.

3. Hydrating the chambers

- Fill a clean syringe with (drinking) water.



- With the valve assembly in the straight **UP position**.
- Insert solution into the flow cell.
- Let stand for 5-10 minutes.

4. Flushing the flow cell

- Place valve assembly in the **HORIZONTAL position** (pointing toward the flow cell).
- Filling a clean syringe with distilled water, and inject water into the flow cell.
- Fill the syringe with air and push the remaining water out of the cell.

5. Flushing the valve assembly

- Place the valve assembly in the **DOWN position**.
- Inject one or more full syringes of distilled water into the valve assembly.
- Fill the syringe with air and push the remaining water out of the cell.

Perform Calibration

- 1) Launch the Thyrodine program by double clicking on the TD.exe icon on the desktop, then click OK.
- 2) Place the valve assembly back in the **UP position**.



Valve Lever in UP position

- 3) To avoid contamination of the whole calibration solution, pour some 1PPM calibration solution into the solution bottle cap.
- 4) Using the 3 cc syringe, draw 1 cc sample of 1ppm calibration solution into the syringe.
- 5) Push down and twist clockwise to secure the syringe into the valve lure fitting on the sample cell.

- 6) With the valve up, gently push down to fill the test cell until the solution just appears at the top of the overflow tube. You may push more solution thru if necessary to remove any air bubbles.



Overflow Tube

- 7) Pull the syringe back up to withdrawal all solution back into the syringe and dump solution in syringe into the sink or waste container.
- 8) Again draw another 1cc of the 1PPM solution into the syringe and gently push down to fill the test cell until the solution just appears at the top of the overflow tube.
- 9) From the Main Menu, click on the “1PPM Calibrate” button, and then click OK.
- 10) A time clock will count down until test is complete. After about 20 seconds, the screen will show the millivolt value for the **1 PPM solution. Acceptable range is 5-90 millivolt.**
- 11) If values fall outside the acceptable range, an instruction on how to clean the sensor will appear. Cleaning the sensor with the cleaning solution provided.
- 12) If you get an error message, rerun calibration step 4 –10
- 13) Remove the syringe and turn valve horizontal toward the flow cell, pump air into the overflow.
- 14) With valve down, pump air out of the drain tube.
- 15) With valve up, wash cell with the 100PPM calibration solution.
- 16) Repeat step 3 - 8 for the 100 PPM calibration solution.
- 17) Acceptable ranges for the 100 PPM calibration is 105-230 millivolt.**
- 18) Calculate the differential value by subtracting the 100 PPM calibration from the 1PPM calibration in millivolt. It is important that the **differential between the 1 PPM and 100 PPM standards be within 85-130 millivolt.** If not, clean the sensor with the cleaning solution. If the value is over 200 millivolt, an error message to clean the sensor will appear.

- 19) Flush the sample cell and valve at least 3 times with distilled or R.O. water to remove any traces of the 100 PPM calibration solution. Discard used calibration solutions. DO NOT put solutions back into the bottles as this may cause contamination of the prepared calibration solutions.
- 20) Save calibration data by clicking on save as and save file as a (for example, 1ppm.csv), then create a folder for the thyroid calibration data, name the file and click OK. Values will now show up on the computer screen.

Testing Patients

An eight (8) hour fast is recommended for best results. If no food or water is taken after midnight and before samples are collected in the morning, the body chemistry will be a better representation of the residuals.

Running Fluid Sample

The instrument is now calibrated for the day and is ready to test body fluids. Note: Never leave samples sitting in the flow cell. Fluids adhering to your sensors can adversely affect them, possibly causing permanent damage and resulting in inaccurate readings.

From the Main Menu, click on “Client Test”. Enter the client’s name. Click “OK”.

1. Testing Sample (Saliva, Urine & Whole Blood)

- a. Draw 1cc of the fluid to be tested into a clean syringe.
- b. Turn the valve assembly lever in the **UP position**. Twist the syringe and turn clockwise to secure the syringe into the valve lure fitting on the sample cell.
- c. Gently fill the test cell until the fluid (about 1 drop) just appears at the top of the overflow tube as shown. Remove any air bubbles by continuing to push fluid through and taking a paper towel to remove the excess fluid.
- d. Click on the white button next to “Saliva, Urine or Blood”, then click “Start” to begin analyzing the sample.
- e. The grey bars will transverse across each of the three-analysis parameter.
- f. When the task is successful, all the values will appear in the tables section.
- g. Remove the sample from the flow cell and flush the cell and the valve assembly with water and air.



- h. A pop-up will appear to save results. Name file, then press OK.
- i. The report screen will appear. You have the option to “Print” or “Close” to return to your main menu.

Note: Only one client’s results can be saved to the clipboard at a time and the analyzer will not permanently store your client’s analysis results. Therefore, you must print out each analysis results immediately following the completion of the analysis. Beginning a new analysis under a new client will automatically erase your existing data.

- To print, click “Copy to Clipboard”, and then click “Print”.

Result Interpretation

Normal Value

Urine	> 1200 ug/dl
Saliva	≥ 2400 ug/dl

To obtain result in PPM, simply divide ug/dl by 100 (100 ug/dl = 1 PPM). The ideal iodine ratio of urine to saliva is 12 to 24 PPM.

End of Day Shut-down & Storage

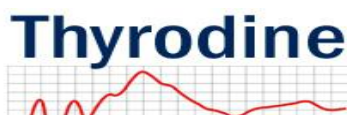
After each use, flush system with distilled water to clean. For overnight storage, add the storage solution to the test cell and do not remove the cell. Turn the valve lever down to keep the solution in the cell.

For long term storage (over a week), remove the electrode and store in the storage solution in the rubber boot provided or small container to reduce evaporation. Do not let the flow cell go dry due to long periods of inactivity. Keep the sensor in the flow cell. Store the system at room temperature, preferably out of direct sunlight.

Maintenance

Flow Cell

The flow cell is one of the key components of your device. It houses the sensor and allows fluids to be placed within for calibrating, validation and analyzing.



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- Do not over-tighten the overflow chamber or valve assembly into the flow cell. The flow cell is made of durable clear acrylic, but it can crack. Some cracks may actually create a leak and will necessitate replacement of the flow cell.
- The flow cell should be cleaned periodically by submerging the flow cell in a warm solution of dishwashing liquid, water, and clean thoroughly as you notice that it is becoming dirty or discolored. Remember to disconnect the sensor from the sensor harness and carefully remove the entire sensor from the flow cell and placing the grey protective caps back on to avoid accidental damage. Again, do not handle the sensor at the glass ends.

Sensor Harness

Periodic examination to ensure harness is not frayed, stressed or showing any wear. If they are, immediate replacement is required. When connecting the harness to the ADCM or electrodes, make certain that the connector is not twisted around repeatedly. Occasionally wipe the sensor harness with a damp moist cloth that will keep it clean and attractive.

Valve Assembly

Fluid or salt residues that have been left un-cleaned in the valve can cause the valve to freeze in place and become very difficult to turn. Keep the valve dry internally by turning the valve in the DOWN position and pushing two or more syringes full of air through the assembly.

ADCM

The ADCM is made of high-grade aircraft aluminum. Never submerge the ADCM in water. The ADCM should always be connected to a certified, fused surge protector. Recommend cleaning procedure include a wipe-down of the unit with a moist (not dripping) soap and water solution, follow by hand drying with a clean cloth. Never place any items, especially electronic items on the ADCM.

Sensor

Continual hydration of the sensor will prolong the life and performance of the sensor. Proper care for the sensor includes flushing of sensor thoroughly with distilled water after each analysis. Use the cleaning solution at the end of each day and again thoroughly flushing the flow cell with distilled water. Once a month (or as needed), carefully remove the sensor from the flow cell by disconnecting the sensor harness connection, and turning the counter-clockwise. Soak the sensor for 5 minutes in a dishwashing liquid and water solution. Rinse thoroughly with distilled water and then hydrate in pH 4 for 5-8 minutes.

If your analysis volume is heavy, this cleaning may need to be performed weekly.



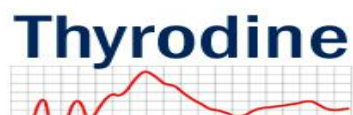


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NOTE: The electrode is an expensive item and will give at least one year reliable service if treated properly. If treated properly, the electrode may last several years. If the electrode does dry out, soak the tip in distilled water for 4+ hours to try to recover its reference cell.



Troubleshooting

If your questions are not answered here, please contact Technical Support.

Q: Why is my Thyrodine software asking for a serial number?

A: A serial number is required to access the software for the first time. Serial number (case sensitive) can be found on the front cover of the CD cover.

Q: Why will the meter not initialize?

A: The ADCM is not receiving power. Unplug the AC adapter from the surge protector and from the back of the ADCM. Re-plug the AC adapter into the ADCM, and then re-plug the AC adapter into the surge protector. If the ADCM is receiving power, there will be a “chirp” sound. If still no power, try replacing the surge protector. If still having problem, the serial cable may not be connected properly, un-plug and re-plug both ends of the serial cable to insure a good connection.

Q: Why is the measurement not stabilizing?

A: There are several possible problems.

- The wrong solution may be in the flow cell. Flush the flow cell and valve thoroughly and inject fresh solution into the valve, then recalibrate.
- There may also be an air bubble in the sample. Flush the flow cell and valve assembly, and inject a fresh sample of solution into the valve assembly. Inject solution slowly until the solution covers all of the sensors, pulling the plunger of the syringe up and down a few times to release air bubbles.
- There may be a contaminant in the samples. Flush the flow cell and valve assembly thoroughly. Use a new syringe and a fresh sample of solution. Inject the solution slowly into the valve until the solution covers all the sensors.
- There may be a residual of cleaning solution or another solution in the flow cell or valve assembly. Flush the flow cell and valve assembly thoroughly. Inject a fresh sample of solution into the valve.
- A static charge may have built up in the ADCM. Step away from the ADCM and the computer. Touch something metal to discharge your static build up.
- Sensor may be faulty and needs to be replaced.

Q: Why is the difference between the differential value for the 1 and 100 PPM low (85-130 millivolt)?

A: The sensor may need to be cleaned. Clean the sensor and sample cell with the cleaning solution. Hydrate with pH4 buffer solution and recalibrate. Other possible problem will be the use of the wrong solution in the flow cell. Flush the flow cell and valve assembly thoroughly and put in fresh solution, then recalibrate.



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Technical Support

For technical support, please call or email to:

Sales & Support **(480) 688 - 6900**
Email support@nitekmedical.com
Website www.nitekmedical.com

Return Instructions

All returns must be requested by calling the Support group at **(480) 688 - 6900** or by emailing us at support@nitekmedical.com. Once you receive the Return Authorization (RA) number from us, please pack the Thyrodine in its original box and packing. Send the Thyrodine to the following address:

NiTek International Inc.
10575 N. 114th St., Suite 103
Scottsdale, AZ 85259 U.S.A.

Please allow us 30 days after the receipt of your return device to process your security deposit. We recommend you returned the device within 2 weeks from date of request to avoid being charged the full monthly minimum fees.

