Installation and User Instructions

Infrared Thermal Thermometer Device Model Tytron / Series C-5000

Classification Name: Powered direct-contact temperature measurement device Common/Usual Name: Computer Aided Paraspinal Thermographic Scanning System Classification: FDA - Class II (USA) CE - Class I – Measuring (Europe)

Model:	TyTron	Specifications: Displayed Temperatures Accuracy+/- 1
degree C		
Series:	C-5000	Differential 0.1 degree C resolution Distance
Odometer +/-	0.25 CM	
Useful Life:	7 years mfg. listing	g.

Product Description/Intended Use:

The C-5000 is a paraspinal infrared temperature recorder (K974208) indicated for use in detecting, measuring, recording, and graphing the skin surface temperature on both sides of the spine of adults and children by chiropractors. It is to be used before and after therapy is rendered as part of monitoring the patients response to care, similar to a common thermometer.

The TyTron series of scanners (C-5000 USB replaces the earlier serial connected instruments) - differed only in the communication mode to the host computer. They directly enter the patients thermographic information into a computer. A built-in distance measuring encoder removes any risk of the operator's inability to control a uniform speed at which the back scan is performed. The scan is initiated at S1 for a full spine graph and C1 for a cervical graph. The end point of the scan is established by the probe tips "bumping" into the occipital shelf. All graphs are than precisely aligned from that end point down, yielding an accurate, repeatable rendering of the thermal "picture" at that point in time of the patient's paraspinal area.

The system is capable of recording and graphing thermal differentials (right to left thermal asymmetries) as displayed on the computer's monitor. It also records actual skin temperature on the right and left sides of the spine.

The sensors are housed in a solid block of aluminum in order to maintain peak efficiency and thermal stability throughout each scan. The focusing barrels are isolated from the patient by their plastic contoured tips. Accurate temperature readings can be taken up to 1 inch away from the skin's surface.



Month 2008 Version

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All pertinent state, regional, and local safety regulations must be observed when installing and using this product. For reasons of safety and to help ensure compliance with documented system data, only the manufacturer shall perform repairs to components.

When devices are used for applications with technical safety requirements, the relevant instructions must be followed.

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Year	Туре	Modifications	
1996	C-3000	An ergonomic handle was added / serial interface added	
2000	C-4000	PIC processor - true RS-232 Serial Communication	
2007	C-5000	FTDI Serial – USB IC added for USB direct interface and power, odometer wheel brackets upgraded to machined aluminum, fiber optic wheel target distance odometer replaced with miniature LED/Sensor IC in wheel hub.	
2012	C-5000 – 3 volt	The scanner "head" and computer board parts were updated to operate on a 3.3 volt power supply.	

Product Modifications

Document Revisions

Date Version Number Document Changes	Date		Document Changes
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2/27/1998	Revision #2	Tytron C-3000 – first owner's manual released - covered installation and key functions of entering patients and saving scans. A trouble shooting guide was included.
11/15/99	Rev 11	TyTron C-3000 Win 95/98 - was updated as software functions and screen displays (NCM meter face for indication of differential readings) and Fossa reading ability.
10/1/2001	Rev 13	Tytron C-3000 Win 95/98/ME/2000/XP installation instructions added for the new versions of Windows operating platforms. Finding com port numbers and checking connections was made easier with newer user interface screens. Importing and Exporting of patient data base scans was made to be user friendly.
3/11/2019	PM.B.004.K1903	Operation and indication of use of the C-5000 was identical to that of the C-3000. The software is still referred to s the C-3000 Tytron Software. Manual revisions reflected added features, especially reports and types of graphic displays that could be chosen (displaying temperature data over a back or x-ray image for example).

Approvals This document requires following approvals:

Name	Title
Joseph Titone	President
Cathy Nelson	Quality Coordinator
Chris Harmon	Vice President – software engineer

Distribution

This document has been distributed to:

Name	Title	
Titronics Customers	The manual is online, customers may call and request previous versions, however in almost all cases the customers take advantage of our automatic software upgrades allowing the current manual and our tech department to be very efficient and effective in handling questions.	
Titronics distributors and Agents		

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1 PREFACE

1.1 Description of the User

The **Type 1 user** would be any health care professional, professional assistant, or chiropractic / medical office employee. The only requirement is that he/she have basic computer skills (minor word processing and familiarity with a computer keyboard). Operation of the instrument involves holding the C-5000 scanner either right or lefthanded, positioning it on the patients' back, pulling and holding a trigger to initiate and complete a rolling scan. Either cervical or full spine scans all end when the probe tips reach the occipital ridge – an easy landmark (the probe tips can't really go beyond this ridge without a conscious effort by the operator to "ride" over the ridge. The exam room temperature should be between 70- and 77-degrees F. (21C to 25 C) The operator training on the actual performance of the rolling scan is shown on a video on our web site <u>www.titronics.com</u> , the operation of the software is described in this owner's manual and can be augmented with real time remote connection using <u>www.gotomeeting.com</u> and Titronics tech team.

Installation of the software maybe done by most lay persons following the directions in this manual. The C-5000 USB driver will self-install the required driver on any Windows computer connected to the internet.

Type 2 user - If multiple computers and a server for the data base are involved, it is customary for an office IT person to perform that part of the setup or an internet connection can be made with the Titronics tech team using www.logmein123.com for remote access.

Only users that have HIPPA training and their office's clearance should be allowed access (passwords) to the software as the patient's name can be seen. The software is password and level protected.

This document is intended for the **Type 1** user.

1.2 Conventions Used in This Manual

The following style conventions are used in this document:

Bold – headings and specific keyboard keys to be used, specific locations on the display graphs.

Temperatures are displayed in Centigrade units. (Change to English units is optional).

Distance is displayed in mm units of measure.

1.3 Explanation of Safety Warnings

Danger indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury

Warning indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.

Caution indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates information considered important, but not hazard-related.

1.4 Retaining Instructions

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in not being able to perform consistent thermal graphs and proper analysis of said graphs not to mention your frustration if any data is lost due to user error.

Ensure that each person who uses the product has read these warnings and instructions and follows them.

Keep all safety information and instructions for future reference and pass them on to subsequent users of the product.

The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the safety instructions. In such cases, the warranty will be voided.

1.5 Obtaining Documentation and Information

1.5.1 Internet

The latest version of the documentation is available at the following address: <u>http://www.titronics.com</u>

1.5.2 Ordering Documentation

Where multiple devices are supplied to a single user and/or location, additional copies of the instructions may be ordered free of charge (please cover shipping outside of the USA).

Documentation, user instructions and technical information can be ordered by calling Titronics R & D at [319 545 7377 EXT 2 or EXT 3]. Documentation can also be downloaded from <u>www.titronics.com</u>.

1.5.3 Other languages

This is the English user manual. Manuals in other languages may be requested when available.

1.5.4 Documentation Feedback

If you are reading Titronics R & D product documentation on the internet, any comments can be submitted on the support website. Comments can also be sent to [roger@titronics.com and <u>dochoskins@titronics.com</u>]. We appreciate your comments.

1.5.5 Support and service

For information about special tools and materials please contact:

Titronics R & D , 400 Stephans Street Unit D, Tiffin, Iowa 52340 USA

Phone 319 545 7377 or through the <u>www.titronics.com</u>

For other questions, information, technical assistance or ordering user instructions, please contact:

Titronics R & D , 400 Stephans Street Unit D, Tiffin, Iowa 52340 USA Phone 319 545 7377 EXT 1

For service-related questions, contact:

Titronics R & D , 400 Stephans Street Unit D, Tiffin, Iowa 52340 USA Phone 319 545 7377 EXT 2 or EXT 3

1.5.6 Name and address of the manufacturer

The company to which this user manual applies, suitable for use within the European Union and is considered to be the manufacturer of the device: Titronics Research & Development, 400 Stephans Street Unit D, Tiffin, Iowa 52340 USA 319 545 7377

2 Description of the product

2.1 Device Description

The TyTron C-5000 is a handheld paraspinal thermographic scanning system. It consists of two focused infrared sensors designed to straddle the spinal column to detect temperatures. With the aid of a computer assisted program, the system is capable of recording and graphing thermal differentials (right to left thermal asymmetries) on a horizontal scale. It also records direct temperatures on the vertical scale (independent at right and left absolute temperatures). Two sets of small wheels incorporate an optical system which measures wheel rotation, providing an accurate odometer for measuring distance traveled along the spine. Full spine scans are conducted and can be graphed as either a full spine line graph or a bar graph. A full spine graph can be achieved in about 15 seconds. The sensors are housed in a solid block of aluminum in order to maintain peak efficiency throughout each scan. The focusing barrels are isolated from the patient by their plastic contoured tips. Accurate temperature readings can be taken up to 1 cm away from the skin's surface.

2.2 Intended Use and Reasonably Foreseeable Misuse – see page 1

2.3 Recommended Cleaning

There are two materials that touch the patient: The distance measuring wheels are an elastomeric "rubber" formulation that is bio compatible. The polycarbonate clear tips on the focusing barrels are also bio compatible. The finish on the scanner is a Polyester Polyurethane baked on coating (powder coat trade name) that is also bio compatible. The concern for skin contamination is in the possible transfer of any infectious microorganisms between patients. The barrel tips sometimes contact the skin in finishing the cervical scan, the measuring wheels are in constant contact during the 3-6 second rolling scan of the patients back.

The use of a germicidal disposable wipe is an excellent tool to minimize the risk of patient to patient or doctor to patient contamination. An intermediate level disinfectant wipe (a premoistened wipe designed to be compatible with nonporous surfaces and equipment made of plastic, rubber, aluminum and more.) is an excellent tool with which to "wipe" down the scanner barrel tips, wheels, and handle. Medical offices perform wipes of equipment and surfaces that will come in contact with patients. Most offices will do a thorough "clean down" at the end of the day. A quick "wipe" of the barrels and wheels after each patient would easily allow 2-minute contact time against enveloped/ non-enveloped viruses, bacteria, TB, fungi, multi-drug resistant organisms and bloodborne pathogens to be destroyed.

2.4 Process Overview

Install the Tytron C-3000 software, then the scanner - follow prompts.

2.5 Recommended System Requirements

For new installations of the Tytron software, we recommend a PC running Windows 10.

Any computer running Windows 10 (Mac with Parallels app) will work.

Both desktop and laptop PC's are suitable but a screen resolution of at least **1024 x 768** is required to display the software correctly so netbooks with a smaller than 10" screen are not recommended. The program is password protected, the data base is encrypted, and higher levels of security can be enabled for multi-users in larger offices / schools.

2.6	Fechnical	Data
-----	------------------	------

Parameter	Unit
Device name	Tytron C-5000 Para-spinal Thermal Scanner
Designation	C-5000
Туре	Infrared Temperature measuring
Technical life span	7 years
Expiry Date	Unknown > 20 years
Capacity	2 Temperature reading focused barrels
Energy consumption	500 milli watts
Mass	0.003108 slugs
Weight	1.6 ounces
Chemical composition	Aluminum
Performance data	Measures 30 to 38 degree targets to +/- 1.0 C
Supply data for power	5 volts DC (USB port) 100 ma
Emissions	None – it' only a measuring device

2.7 Product Compliance

This product complies to all relevant European Directives. The Declaration of Conformity can be found in the appendix. The Product is in conformity with the following relevant product safety standards.

2.8 Summary of Safety and Clinical Performance

- C-5000 mfg. by Titronics Research & Development UDI-ID 00860447001714
- Device measures skin temperature there is no contraindications for use on the general public.
- The C-5000 is the USB connected version of the previous Serial Connect C-3000 and C-4000 instruments that required Serial to USB converters.
- The C-5000 requires a host computer and display screen for its operation .
- Harmonized Standard Code 9025192000 Thermometers

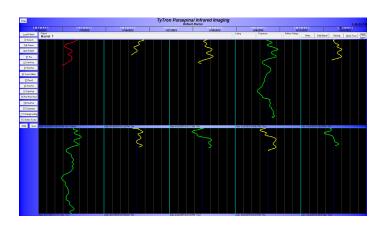
The Summary of Safety and Clinical Performance is available at the following address: HTTP/www.titronics.com

3 Tytron C-5000 Operating Instructions

ELEMENT A - Scanner



ELEMENT B – C-3000 Software Program



The C-5000 has one control -a "trigger" switch that alerts the monitoring computer that a thermal scan is being performed. The "trigger" is depressed during the scan from the lower back to the occiput. The left rolling wheel measures the total distance scanned and must contact the skin during the "scan".

The software acknowledges the "trigger pull" with a "BEEP.

3.1 System Components

Verify Receipt of All System Components

Your Tytron System includes the following if your Tytron serial number begins with a **5xxxx**:

- Tytron Scanner (5xxxx)
- 2 USB Cables
- Tytron Scanner Holder
- Tytron Software Installation Media (Includes Calibration File, Drivers, Manual, Clinical Interpretation Book, Articles and Poster)
- Repair Kit

System Requirements: Windows 7/8/10 • Pentium II Processor or Greater •200MB Free Hard Drive Space, a USB Port for installation and at least 1 USB port for scanner connection.

- Use the supplied desktop scanner holder to avoid Tytron drops. Remember to keep the cord out of walking paths. For drops, use the repair kit and instructions. Adhesives **should not** be used for repairs.
- Perform periodic maintenance on the Tytron. The scanner barrels may accumulate dust and dirt particles over time. For small amounts of debris in the barrels Titronics recommends using canned air (available at most electronics stores). Insert the spray straw approximately 1" into the barrel. Spray for three seconds. Allow the unit to sit for 15 minutes. Do not insert the straw deeper than 1.5" into the barrels -- touching the lenses with the straw could alter the calibration of the precision sensors! For cleaning instructions and additional information refer to the Appendix page XXX.

When the C5000 trigger is pulled, a white light will show on the handle of scanner to indicate the scanner is receiving power.

• The Tytron uses the left inner wheel for distance measurement. Keep this portion of the wheel in contact with the patient for accurate results. Do not scan over the patient's clothes. Ensure the scanner sensors have a direct view and contact of the patient's bare back.

• The Tytron should be kept in a 70° F (21 Centigrade) - 80° F (26 Centigrade) temperature environment for optimal performance.

- Ensure the Tytron isn't sitting directly next to a computer or other heat source. Titronics recommends providing 10 inches of space between the Tytron and the computer. Ensure the Tytron isn't resting in direct sunlight or next to an open window. Keep the Tytron away from heating and cooling vents. This will insure balanced readings on the screen.
- **Regularly backup the database.** Titronics recommends weekly backups and storing the backup on a flash drive.

3.2 Tytron C-5000 FAST SETUP

Insert the Flash Drive with the C-3000 software on it. Double click Titronics.exe below:

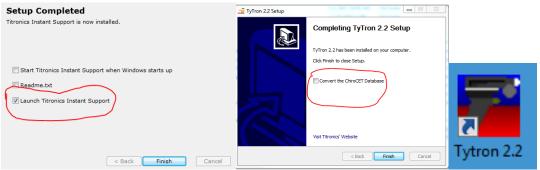
Setup.dat	9/10/2014 2:34 PM	DAT File	1 KB
📷 Software Install - Data Base Procedures.doc	1/7/2016 3:23 PM	Microsoft Word 9	852 KB
📑 Titronics.exe 🔶	10/11/2013 1:12 PM	Application	852 KB
🔁 TytronManual.pdf	8/11/2016 1:44 PM	Adobe Acrobat D	12,385 KB

Double click Install Scanner Software:



Accept all the defaults. Ignore these warnings as shown below. If they come up – choose **Yes** or **OK.**

After Titronics Instant Support is loaded you may **uncheck** the Launch option if you don't want to connect immediately (you should not need to unless your C-5000 scanner doesn't connect automatically over the internet). On the next screen just click **Finish.**



Double click the Tytron 2.2 icon to launch the program, click Setup (upper left) and enter:

Doctor Information
Doctor's Name: roger
Address Line 1: Default Office
Address Line 2: Default Office
Registration Number: 134251378

134251378

Click **OK**, go back into **Setup > Scanner** tab,

In the USB Scanner 1 box it should say: (calibration numbers should agree with enclosed calibration report numbers)

Setup for Tytron C-30	00 v2.2.1.2	x
Main Scans Printing	Scanner Connect to S	Support
USB Scanner 1	-Wireless Scanner Settings]
Scale Factor 0: 983	Offset D: Detected scanner #51074	
	Offset 1: 214 Trigger Pulled / cause problems if you	
Scale Factor 2: 979	Offset 2: 6	
USB Scanner 2	Timeou(seconds), j	
Scale Factor 0:	Offset 0: Not Detected Serial Number Key	
,	Offset 1: 50600 Z	
Scale Factor 2:	Offset 2: 50601 K	
Serial Scanner 1		
🔲 Enabled	Devices and Printers Device Mana	iger
	Enable User Co	introls
Check for Updates	AutoCheck OK Cancel	

If **Trigger Pulled** appears when the trigger is pulled proceed to next step. If you are not seeing **Trigger Pulled** refer to the instructions for Loading Drivers. Check in Device manager and check under **Universal Serial Bus Controllers**

Ports (COM & LPT)
 Processors
 Sound, video and game controllers
 System devices
 Universal Serial Bus controllers
 Alcor Micro USB 2.0 Card Reader
 Generic USB Hub
 Generic USB Hub
 Intel(R) USB 3.0 eXtensible Host Controller
 Intel(R) USB 3.0 Root Hub
 Standard Enhanced PCI to USB Host Controller
 Standard Enhanced PCI to USB Host Controller
 Tytron C-5000
 USB Composite Device



Click **OK**, click in the upper right and perform a scan under your chin. If a scan screen comes up and you are able to perform a graph – you have successfully installed your software and C-5000 scanner!

3.3 Using the Tytron Software

The Tytron Software uses several keyboard functions designed to let you work as efficiently as possible. The Tytron Software follows these simple rules:

1. All buttons/functions can be initiated by clicking on them with the mouse. Any underlined letter denotes that the function can be initiated by using the corresponding keyboard key (i.e. F5, <u>L</u>oad Patient, etc.).

2. The Esc key goes back one screen at a time.

3. Basic keyboard commands apply to most functions within this program (i.e. **Tab** key moves through fields, **PgUp/PgDown** moves quickly through lists, etc.).

3.4 Quick Key Commands

The following is a quick summary of the single letter command keys that function either in the scan display, scan history, or home screens:

B =Toggles between the line graph and Bar graph views. (scan screen or bar graph screen)

D =Toggles between the Delta-T and **D**T views. (bar graph screen)

A = Shows Autonomic chart with a bar graph. (bar graph screen)

N = Displays a Normal scan for comparison. (scan screen)

- F = Allows Fossa temperatures to be taken. (scan screen)
- I = Allows Infants scans to be taken. (scan screen)
- **E** = Allows a Segmental scan to be taken. (scan screen)
- L = Place or reposition Break Lines. (scan screen)
- H = Hide or show Break Lines. (scan or history screens)

PgUp/PgDown = Search through additional past scans. (history screens)

P or **R** = **P**rint any displayed scan screen. (scan, bar, or history screens)

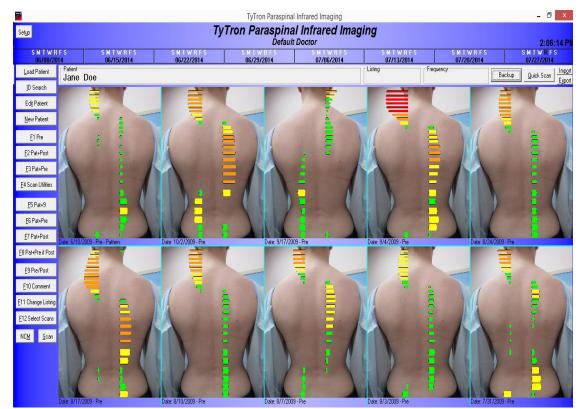
- **S** = Brings up a blank **S**can Screen. (home screen)
- L = Load a Patient. (home screen)
- T = Edit a Patient. (home screen)

M = NC**M** mode. (home screen)

X = Exports the screen as a jpeg to a folder called images in the C-3000 folder. (at any screen showing a scan, bar graph, or history)

- **X** = Export the Patient. (home screen)
- **Q** = **Q**uick Scan a patient without saving the scan. (home screen)
- **O** = Imports a patient. (home screen)
- **U** = Load the Set**u**p screen. (home screen)
- **Z** = Opens the notes on most screens.
- **Y** = Toggles the Delta/DT Hybrid option.
- R = Daily Report (home screen)
- **P** = Backu**p** of database (home screen)

3.5 The Home Screen



The Home Screen (shown above with a patient loaded) is the first screen displayed when the program is started and displays the most common functions and data. From this screen you will be able to perform most of your patient file work and scan viewing in an efficient manner.

Your customization information (based on the information you supplied at the time of purchase and registration for clinic name, your name, etc.) displays below the TyTron program label. You may change this information at any time by clicking on the Setup button and changing the information displayed on the Main tab. The change in the information displayed does not occur until you click the **OK** button.

Patient: Load a patient by clicking on **Load Patient** or **ID Search** or enter a new patient by clicking on **New Patient.** The Patient's name now appears on the home screen.

Listing and Frequency: This optional information may be entered when creating a new patient or editing when a current patient's listing or frequency changes by going to **Edit Patient.**

8-Week Care History: Displays the currently selected patient's last eight weeks of care. The current date displays in black. Any date highlighted green denotes the patient was scanned, but that no adjustment was rendered. A red highlighted date signifies a delivered adjustment. The first scan of the day is marked as a pre; all subsequent scans are marked as posts, unless the F9 key is used to toggle the last scan between pre and post.

This 8-week Care History quickly displays how often the patient is being adjusted; and thus, whether the current adjusting method is or is not appropriate for the patient.

Scan: Once in a selected patient's file, click the Scan key, or hit **S** on the keyboard, to perform a simple scan without a pre-adjustment or pattern overlay. Immediately taking another scan simply overlays the additional scan over the previous scan. **Once you exit the scan window, only the last scan taken is saved in the patient's file**. To save any scan you can also press **Enter** before performing another scan.

3.6 The Setup Screen

The **Setup** button is located in the upper left corner of the home screen. The Setup screen allows for the management of individual preferences in four tabbed areas: **Main**, **Scans**, **Printing**, and **Scanner**.

Note: Do not change the registration number. If you do, your software will go into Unregistered Copy mode and you will not be able to change any of the information in your three lines, nor will you be able to take a scan. If this happens, please contact Titronics R&D at 1-319-545 7377.

3.6.1 The Main Tab Screen

Main Tab: Manages options for Doctor Information, Registration Number, System

Password, Default Search Method, Show File Number, Default History View, Recoup Suites, Saving Scans and more.

Setup for Tytron C-3000 v2.2.1.0	\times
Main Scans Printing Scanner Admin	
Doctor Information	Default Search Method
Doctor's Name: Titronics R & D	 By Last Name By File Number
Address Line 1: Tech Supprt	Search First Names
Address Line 2: 1800-705-2307	Show File Number?
Registration Number: 134251378 Load Registration/Calibration	
System Password Quick Scan Name Quick Scan	Default History View C-Spine & Full Spine
Recoup Suites Number of Recoup Suites: 0 Initials in List I ID in List Alternate Sound	C <u>C</u> -Spine Only C <u>F</u> ull Spine Only
Database Settings Auto-S Data Folder: C:\C3000\db Browse Backup Check Auto-S 	ave with no comment ave and ask for comment mly if a comment is entered
Home Screen Scans Default Custom Image Image Default Image Location: Image Default Image Location: Image Default Image Default	Sound Yes No
Check for Updates AutoCheck OK Cancel	

The **Check for Updates** button will connect over the internet to see if a new version of the software is available. If the **AutoCheck** box is checked it will check for an update when the program starts.

The **System Password** section can be set by entering alphanumeric characters. Leave this field blank to disable the password prompts. If a password is entered, please remember this password to log into the Tytron software and/or store the password in a safe place.

The **Default Search Method** section determines the default patient search method, by last name or file number.

The **Show File Number** section allows the option to display the patient file number next to their name for quick reference.

The **Default History View** section determines how scans display in the 10 Scan History screen. Display options are view C-Spine and Full Spine scans together, C-Spine scans alone, or Full Spine scans alone.

The **Recoup Suites** section allows the display of up to 300 post-adjustment suites on the Home Screen. Simply enter the number of suites in the office. If post-adjustment recoup suites are not part of your patient care, enter 0 in the field and the recoup suites will not appear on the Home Screen. You have the option to put names, initials, or ID numbers in the recoup space. You can also select between 2 alert tones.

The **Saving Scans** section determines how the Tytron software handles saving scans. Titronics recommends to always use one of the Auto-Save options.

- Auto-Save with no comment saves all scans without prompting for comments.
- Auto-Save and ask for comment saves all scans and prompts for comments.
- Save only if a comment is entered prompts for comments and only saves the scan if a comment is entered.

Screening Mode points the software database away from a networked database to a local drive on the screening computer.

3.6.2 The Scans Tabs Screen

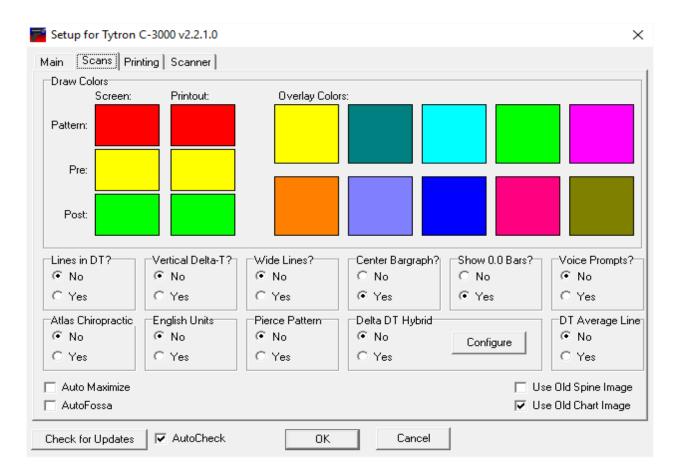
Manages options for Draw Colors for Line graphs, Lines in DT, Vertical Delta-T, Wide Lines, Center Bar Graph and Voice Prompts.

The Draw Colors section determines the colors used when displaying line graphs. Up to 10 line graph scans may be overlaid. Simply click the Other Scans color to select the color for that scan. This option is helpful for colors that might be hard to see on the screen. The Pattern, Pre and Post colors display on screens where the scans are not overlaid.

The **Lines in DT** section places white vertical background lines on the right and left graphs (similar to those displayed in the Center Delta-T bar graph) for each degree (30°, 31°, etc.).

The English Units selection allows the software to use English units.

Pierce Pattern option allows you to select multiple scans as pattern in a patient's file.



The **Vertical Delta-T** section displays, at the top of the graph, the vertical direct temperature differential for each side calculated as the temperature difference between the lower and upper 2 cm of the graph. An ideal graph would show a gradual increase in temperature from the sacrum to the occiput. Ex: VDT: T 1.25.

The **Wide Lines** section displays wider/thicker lines for line graph scans.

The **Center bar graph** section centers the displayed bars over an implied zero center (vertical blue line in line graph view). This feature is useful when performing scans outside the office. Temperature gradients across the scanner can alter the zero position of the line graph, presenting a misleading bar graph (all the bars off to one side). **Note:** The default is set to No; this is the best way to monitor the scanner calibration and when you need to "clean" the barrels when in a controlled environment such as your office.

The **Show 0.0 Bars** option toggles whether bars with a value of 0.0 are displayed on bar graphs.

The Voice Prompts section provides voice prompts to operate the scanner.

Atlas integration allows the software to be used with Atlas Chiropractic Software. Contact Atlas for information about configuring their software to integrate.

Delta DT Hybrid and DT Average Line options allow the display of scans with Delta DT information shown. DT Average Line toggles whether the DT average is shown. The "**Y**" key toggles the feature on & off while viewing patients' line graphs. The configure feature allows you to change the colors of the Delta DT Hybrid screens.

Setup for Tytron C-3000 v2.2.1.15		×
Main Scans Printing Scanner		Connect to Support
Print Colors		
Default Comment:		Use MAPI(Send using client) Body
Symptoms/Diagnosis on printouts?	Language	E-Mail Settings(SMTP)
		Server:
C Yes	C F F F F F F F F F F	Port(SSL): 0
Default Printout	English Standard	User Name:
 With Narrative Without 		Password:
Check for Updates AutoCheck	ОК	Cancel

3.6.3 The Printing Tab Screen

The **Print Colors** area determines the colors used when printing up to 10 overlaid Line Graph scans. Simply click the scan color to select a color for that scan.

The Language section defaults to English Standard.

The **Symptoms / Diagnosis** section allows the addition of a generic symptom and diagnosis to printouts.

Note: Colors can vary from screen to printouts. This tab helps optimize printout colors.

The Use **MAIP** option will use your Email client (Thunderbird, etc.) to send mail.

The **E-Mail Settings (SMPT)** area allows you to configure the software to send mail directly through your E-Mail server. Consult with you E-Mail provider for information on these settings.

3.6.4 The Scanner Tab Screen

Main Scans Printing USB Scanner 1	Scanner Admin		Wireless Scanner Settings
Scale Factor 0: 959	Offset 0: 36 Offset 1: 127	Detected scanner #70004	 Wireless AutoScan Enabling this option may cause problems if you
Scale Factor 2: 1014	Offset 2: 28	Copy Calibration	have multiple recievers. Timeout(seconds): 3
USB Scanner 2			Dual Wireless Mode
Scale Factor 0:	Offset 0:	Not Detected	Serial Number Key
	Offset 1:		50600 A
Scale Factor 2:	Offset 2:		50601 K
Serial Scanner 1			
🔽 Enabled	Offset 0: 36	Detected COM4 Device	es and Printers Device Manager
Scale Factor 0: 959	Offset 1: 127		
Scale Factor 2: 1014	Offset 2: 28	Port Number: 4 Load Registration	on/Calibration List Ports
Serial Scanner 2			
Enabled			

The Calibration Settings should not be changed at any time unless instructed directly by Titronics Technical Support. These values are set at the time of software installation and are unique to each scanner.

The Wireless Settings area is available for wireless scanner use onl

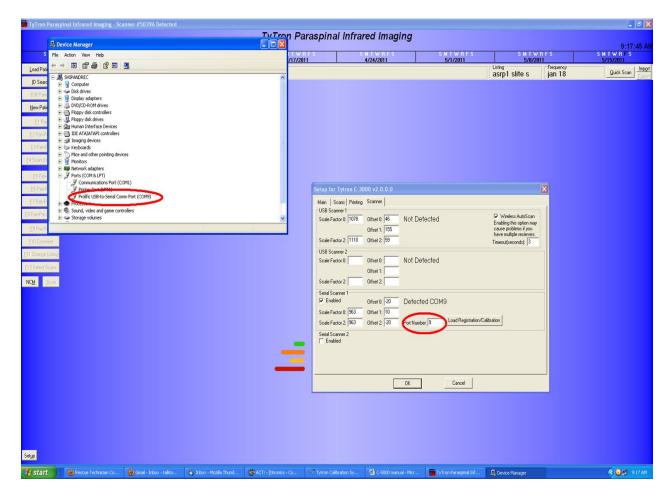
For older Serial connected Tytron scanner:

The List Ports button shows all ports available.

The **Show Device Manager** button takes you to the computer's Device Manager. The **Device & Printers** button takes you to the computer's Device & Printers.

The Scanner Port area (if applicable) allows the selection of a USB port(s) to use in conjunction with a USB adapter. This selection directs the Tytron software in correctly

finding the Tytron. This option is selected during installation. However, if the Tytron is not scanning, it may be registering on a different virtual port than it originally did when you last used it. To fix this problem, go to the device manager and find the port that the scanner is registering under, then make sure it is the same port as in the software.



Checking in the Device Manager for the correct serial port:

3.7 Patient Management

3.7.1 Entering a New Patient

To enter a new patient, click the **New Patient** button or hit the **N** key at the **home screen**. The patient's first and last name must be entered. All other information is optional. To display a patient's Treatment Frequency and Adjustment Listings, fill in those fields in the Patient Settings section.

	New Patient
Patient Information	
Last Name:	First Name:
File Number:	
Address 1:	
Address 2 / Email:	
City:	State: Zip:
Phone:	
Patient Settings	
Frequency:	✓ Listing:
Symptoms:	
Diagnosis:	
Re-Evaluation every	weeks from
Doctor:	
Technic	sian:
	Cancel OK

To print reports containing the patient's clinical information, fill in the Symptoms, Diagnosis, and Technician areas in the Patient Settings section. This information provides information requested by many insurance companies.

The Re-Evaluation area serves as an automatic reminder function for re-evaluations. The first, drop-down arrow box determines the rate of re-evaluation (1x/week, every 2 weeks, every 4 weeks, etc.). The other field allows for referencing a start date (i.e. re-examination 4 weeks from this date). The current day is automatically entered. If the frequency field is blank, or 0 is entered, the automated re-examination function is turned off. When a re-evaluation date is set, the automatic reminder appears three days before the date of re-evaluation when the patient is loaded on the home screen. To reset this function, use the **Edit Patient** function (described below) and change the frequency and/or date. This removes the Re-Evaluation notice at the patient's home screen.

3.7.2 Editing Patient Information

To edit patient information, click the **Edit Patient** button or hit the **T** key while at the selected patient's home screen. The same screen is presented as when entering a new patient. The most frequent use of editing is to change patient treatment frequency and re-examination times. This area is not for deleting scans or a patient (Scan Utilities F4).

Edit Patient Information	
Patient Information	
Last Name: Doe First Name: John	
File Number:	
Address 1: 400 Stephans St. Ste. D PO Box 470	
Address 2 / Email: info@titronics.com	
City: Tiffin State: IA Zip: 52340	
Phone: 1800-705-2307	
Patient Settings	-
Frequency: Listing:	
Symptoms:	
Diagnosis:	
Re-Evaluation every 0 💌 weeks from	
Doctor: Harmon	-
Technician: Carhoff	
Select Back Image Select X-Ray Image OK	

The **Frequency** (how often the doctor wants to see the patient) and the patient's **Listing** will appear on the home screen. **Symptoms, Diagnosis, Evaluation** visits, **Doctor**, and **Technician** will appear on printout reports.

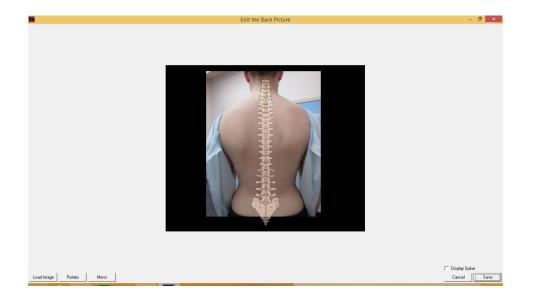
The **Select Back Image** button is used to load images of the patient's actual back that you have previously taken. To do this simply press the **Select Back Image** button then follow these steps:

1. Browse to the image in the box that comes up and click **Open**.

Open					? 🗙
Look in: 🞯	Desktop	* 📫 🔹		(1944x2592)	Q
Jane Doe i Jane Doe 3 img002 img005 img134 img135		💼 img136 🔐 My Computer 💼 photo			
K File <u>n</u> ame:	Jane Doe Back Pic		<u>0</u> pen	1	1
Files of <u>t</u> ype:	All (*.png;*.jpg;*.jpeg;*.bmp;*.ico;*.	emf;*.wmf)	Cancel	K	5

2. On the next screen that appears pull on the corner of the frame around the spine that is super imposed over the patient's picture to lie on top of the patient's actual spine. Note that the sacrum and the coccyx bones can be off of the picture if need be.

- 3. Once you have the spine aligned to correctly match the patient's spine, click **Save** or hit the **Enter** key on your keyboard. The picture is now saved as the patient's back image.
- 4. Make sure that the **Default Custom Image** is set to **Back**.
- 5. Reload the patient to use the new image.



The **Select X-Ray Image** button is used to load images of the patient's X-Ray that you have previously taken. To do this simply press the **Select X-Ray Image** button then follow these steps:

Open						? 🗙
Look in: [Desktop		•	* 🎟 •	(3000x4000)	<u>a</u>
img002 img005 img134 img135 img136 Jane Doe	Back Pic		Jane Doe XRa J My Computer photo	y.		
File <u>n</u> ame: Files of <u>type</u> :	Jane Doe XRa All (*.png;*.jpg	;*.jpeg;*.bmp;*.ico;*.	emf;".wmf) 💌	<u>O</u> pen Cancel		

1. Locate the image in the box that came up and click **Open**.

2. On the next screen that appears pull on the corner of the frame around the spine that is super imposed over the patient's X-Ray to lie on top of the patient's actual spine. Note that the sacrum and the coccyx bones can be off of the picture if need be.

Edit the X-Ray Picture	
f dit the X Ray Picture	
Load image	Cancel

- 3. Once you have the spine aligned to correctly match the patient's spine, click **Save** or hit the **Enter** key on your keyboard. The picture is now saved as the patient's X-Ray image.
- 4. Make sure that the **Default Custom Image** is set to **X-Ray**.
- 5. Reload the patient to use the new image.

3.7.3 Load Patient File

To load a patient file from the Home Screen, click the **Load Patient** button or hit the **L** key. A **Quick Search** pop up appears. Click **Search**, this displays a list of all patients along with a flashing cursor in the patient's last name field (or in their file number field depending on default settings). Enter 1 or more letters of the patient's last name to narrow the search field. Once the patient displays on the screen, highlight their name and click **OK** or hit the **Tab** key to move to the names field and select the alphabetical letter that corresponds to the patient. The patient's name now displays on the home screen.

Quick Search						
Last Name:	Search					

You may also click on Search and find the patient in the list and double click on the name.

	elect Patient		×				
Sea	rch By Last Name	ID Number					
Key	Last Name	First Name	File #				
A	Angelo	Brigitte					
В	В	Ron					
С	J	Mark					
D	ĸ	Andrew					
E	к	George					
F	Lemont	Yves					
G	Pyke	Laurent					
Н	R	Michael					
I	Т	Marvel					
J	Titone	Roger	•				
Exp	port List	Cano	el OK				

3.8 Keyboard Function Keys F1 – F4

These function keys are used to review previous scans.

<u>F</u> 1 Pre								
<u>F</u> 2 Pat+Post								
<u>F</u> 3 Pat+Pre								
<u>F</u> 4 Scan Utilities								
<u>F</u> 5 Pat+9								
<u>F</u> 6 Pat+Pre								
<u>F</u> 7 Pat+Post								
<u>F</u> 8 Pat+Pre if Post								
<u>E</u> 9 Pre/Post								
<u>F</u> 10 Comment								
E11 Change Listing								
<u>F</u> 12 Select Scans								

F1 Pre: Displays the last pre-adjustment scan performed.

F2 Pat + Post: This function serves two purposes. First, a patient's pattern is displayed with the last post-adjustment scan overlaid, allowing the patient to see results of their last adjustment. Second, use the **C** key to look back through post-adjustment scans in detail to determine the effectiveness of adjustments.

F3 Pat + Pre: This function also serves two purposes. First, a patient's pattern is displayed with the last pre-adjustment scan overlaid, to objectively present data supporting your decision along with other findings to adjust or not adjust at visit. Second, use the **C** key to look back through pre-adjustment scans in detail.

F4 Scan Utilities: The Scan Utilities screen has 9 basic functions. Click the **Scan Utilities** button or hit the **F4** key while at the Home Screen to

perform scan utilities. First, a scan must be selected to perform a scan utility function (either click on it or select the corresponding letter) -- the exception to this in the Any 2 Scans function.

7	Scan Utilities 🛛 🥤	_	_	~							ĸ
<u>1</u> Vi	ew 2 Any 2 Scans 2 V	/iew /v	v Pat 4 Pr	e/Post 5_Edit Scan	<u>6</u> Ma	ike Pat	7 Delete Scan	<u>8</u> Move Scan	Delete Patient	Export to	Csv
Key	Date / Time	Pat	Note	Listing	Full	Pre	Comment			Fossa	1 ^
А	8/14/2015 5:12:20 PM					Pre					
В	7/23/2015 2:09:35 PM	Pat				Pre					
С	4/30/2015 8:41:27 AM					Pre					
D	4/29/2015 9:38:42 PM				Full	Post					
E	4/29/2015 9:38:05 PM					Pre					
F	4/27/2015 8:11:11 AM				Full	Post					
G	4/27/2015 8:10:29 AM					Pre					
Н	4/26/2015 8:57:28 PM					Post					
1	4/26/2015 8:53:23 PM					Pre					
J	4/24/2015 8:29:07 AM					Post					
К	4/24/2015 8:28:01 AM					Post					

The "numbered" choice boxes can be chosen by clicking on them or hitting the corresponding numbers on the keyboard.

1 View: Views the selected scan. This can also be performed by double clicking

the scan or hitting the **Enter** key.

2 Any **2** Scans: Displays an overlay of 2 selected scans. Select the scans after hitting this button by clicking on the desired scans or pressing the corresponding letters.

3 View /w Pat: Displays the selected scan overlaid with the patient's selected pattern.

4 Pre/Post: Changes the selected scan from a pre-adjustment scan to a post and vice versa.

5 Edit Scan: Edits the Note, Listing, Comment, Pre/Post designation, Pattern fields and options for a scan. The Note field allows notes up to 4 characters long (i.e. MVA). Editing the Listing changes the listing for the currently selected scan only. The Comment field allows up to 255 characters of information (i.e. SOAP notes).

6 Make Pat: Marks the selected scan as the patient's pattern.

7 Delete Scan: Permanently deletes the scan from the selected patient's database.

Delete Patient: Permanently erases the patient and all their scans. This cannot be undone!

Export to CSV: Exports the scan list to a .CSV (comma separated values) file.

3.9 Keyboard Function Keys F5 – F12

F5 – F8 The History Manager allows for quickly monitoring the details and results of care. Hitting the **Page Up and Page Down** keys while viewing a patient that has more scans than displayed on the screen allows for the viewing the additional scans from the patient's history. The History Manager functions are discussed in more detail in Appendix.

F5 Pat + 9: Displays the patient's chosen pattern in the upper left-hand corner along with the last 9 scans in the database. This allows the ability to review the progress of care and evaluate both the chosen pre-adjustment scan and the effects of the adjustment on the post scan.

F6 Pat + Pre: Displays the patient's chosen pattern in the upper left-hand corner along with the last 9 pre-adjustment scans in the database to quickly evaluate if a new pattern is forming.

F7 Pat + Post: Displays the patient's chosen pattern in the upper left-hand corner along with the last 9 post-adjustment scans in the database to quickly evaluate if rendered adjustments are effective.

F8 Pat + Pre when Post: Displays the patient's chosen pattern in the upper left-hand

corner along with the last 9 pre-adjustment scans when a post adjustment scan is performed. This allows the ability to evaluate if the pre-adjustment scans match the pattern or if over-adjustments are performed.

F9 Pre/Post: Quickly toggles the last scan taken between a Pre and a Post Adjustment.

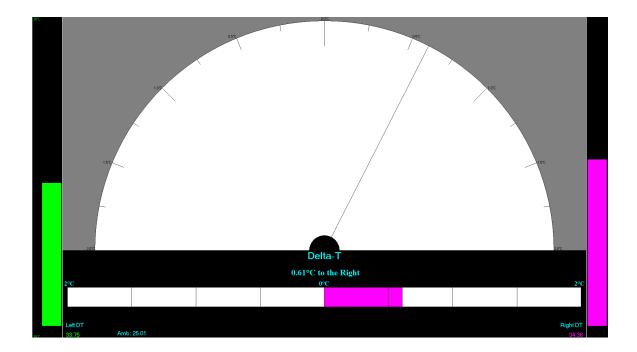
F10 Comment: Displays the comment field for the last scan taken. The comment field allows up to 255 characters of information, for comments such as SOAP notes.

F11 Change Listing: Changes the listing for the last scan taken. This differs from the editing function in the **Scans Utilities** area. This function updates the displayed home screen listing and all subsequent scans performed.

F12 Select Scans: Allows the selection of up to 10 scans for individual history viewing. Once the scans have been selected, click **OK** or hit the **Enter** key to view the scans. Hit the **Esc** key to return to the **Select Scans** screen. Click the **Clear** button to clear previously selected scans or **Esc** again to return to the home screen.

7	Select scans to view in hi	story	form							×	
Key	Date / Time	Pat	Note	Listing	Full	Pre	Comment				^
А	8/14/2015 5:12:20 PM					Pre					
В	7/23/2015 2:09:35 PM	Pat				Pre					
С	4/30/2015 8:41:27 AM	-				Pre					
D	4/29/2015 9:38:42 PM				Full	Post					
E	4/29/2015 9:38:05 PM					Pre					
F	4/27/2015 8:11:11 AM				Full	Post					
G	4/27/2015 8:10:29 AM					Pre					
н	4/26/2015 8:57:28 PM		5			Post					
<u> </u>	4/26/2015 8:53:23 PM					Pre					
	4/24/2015 8:29:07 AM					Post					
ĸ	4/24/2015 8:28:01 AM					Post					
L	4/24/2015 8:27:23 AM				Full	Pre					Υ.
4/26	/2015 - /2015 - /2015 -										
				Clear		Delete	Ca	ancel	0)K	

NCM: Loads the NCM Screen for real time scanning display while scanning the back.



Scan: Hitting the **S** key allows for a simple scan to be taken without a pre-adjustment or pattern overlay. Multiple scans may be performed in this manner, however only the last scan taken will be saved in the patient's file upon exit. To save multiple scans press the **Enter** key after taking each scan.

3.10 Scanning

Before starting the scanning process, please review the preparation involved to perform accurate thermal imaging.

The Tytron Scanner must be run on bare skin, not through clothing. The Tytron Scanner must be run from the bottom of the spine to the top.

Environmental Controls

- The office temperature should be held between 72°-80°F. (22° 27° C)
- No direct cooling or heating vent drafts should bear on the scanner or patient.
- The scanner should not be placed in direct sunlight.

• Place the scanner holder away from the computer to avoid heat being emitted from the PC.

• When outside the office, enable the **Center Bargraph** feature to center the displayed bars over an implied zero center. This feature is useful when performing scans outside the office to neutralize any effects of temperature gradients across the scanner, which might present a misleading Bargraph (all the bars off to one side).

Note: The default is set to disabled; this is the best way to monitor the calibration of the scanner when in a controlled environment such as an office.

• For scanners without power for **more** than 30 minutes, allow a 20-minute temperature stabilization period. Example: Going from outside to inside.

• For scanners without power for **less** than 30 minutes, allow a 10-minute temperature stabilization period. Example: Going from room to room.

• For C-5000 units, ensure the computer is powered on (and doesn't go into hibernate mode after being left idle). If the computer is turned off and on frequently Titronics recommends purchasing a powered USB hub (available at most electronics stores) to maintain power to the scanner.

Patient Preparation

- 15 minutes of office acclimation time must occur before scanning the patient.
- The patient needs to remove any neck ties and necklaces.
- The patient should also remove thick clothing such as a winter coat while acclimating.
- The patient must remain free from direct heating or cooling drafts.
- No direct sunlight should bear on the patient while in the office.
- No EMS, TENS, US, hot or cold packs, or acupuncture before scanning.
- The patient must be free from sunburn.
- A patient may be scanned while sitting, standing or lying face down.
- Although highly recommended, it is not necessary for a patient to completely disrobe. Segmental scans may be performed.

3.10.1 Performing a Scan

Once a patient is selected the scanning process itself is fully automated.

1. Pick up the scanner by its handle. **Do not touch any part of the scanner head.** (This is the area above the handle that is separated by a white or black thermal shield). Touching the scanner head can temporarily affect scan accuracy.

2. Place the wheels on the patient while maintaining the probe tips just above the surface of the skin. Evenly space the probes over the center of the spine. When performing full spine scans, carefully palpate for the first sacral segment and place the probes one centimeter below this level. If only scanning the cervical spine, carefully palpate for the first thoracic segment and begin the scan here. Use only spinous process palpation to locate starting points. Any palpation over the paraspinal surfaces will alter true thermal data collection.

3. Pull the trigger, but **do not begin scanning immediately!** A tone sounds (if sound is enabled), along with a screen prompt reading **Initializing Sensors**. A second tone sounds to signal to begin the scan, along with a screen prompt reading **Scanning**. A voice prompt may also be selected by going to Setup.

4. Begin scanning from the lower back towards the head with an even cadence while maintaining the probe tips just off the skin. When the hairline is encountered, gently press the probes towards the skin to displace the hair. Stop the scan when the occiput is encountered and release the trigger before lifting the scanner off the spine. A proper scan cadence will yield approximately 20 seconds for a full spine and 8 seconds for a cervical spine scan.

Once the trigger is released it will immediately display on the line graph screen. If the patient's pattern or a previous scan has been performed on the same day, the current scan is automatically overlaid. To perform a scan without a pre-scan or pattern overlay, simply hit the S key while at the home screen. Hitting the Esc key or clicking the X in the upper right area of the screen or hitting E**nter** saves the last scan preformed.

The exceptionally high repeatability of the Tytron is dependent upon the scanner's left wheel encoder maintaining rolling contact with the patient through the termination point of the scan. It is recommended that the patient be in the same position/posture for each scan to ensure repeatability. The reference point of each scan is the termination point (with the exception of scanning infants). Thus, the termination point of the scan is established when the scanner's probes reach the occiput.

3.10.1.1 Segmental Scanning

The segmental mode allows performing a lumbar and lower upper neck, while omitting the thoracic region (to avoid clothing). Simply lift the back covering to expose the lumbar and lower the back covering to expose the cervical. To do this, click **Scan** on the home screen to display a blank scan screen. Click the **Segment** button, located at the top right corner of the screen. To record all data properly, place the scanner probes ¾" lower than the desired starting point. To start, pull the trigger and scan the lumbar region, then release the trigger. Next, place the scanner just below T1, pull the trigger again and complete the cervical scan, then release the trigger. The full spine line or bar graph displays with no lines/bars in the mid spine area.

3.10.1.2 Scanning Infants

Scanning infants adheres to the same rules as adults. However, the fixed probe width being wider than an infant's neck necessitates a special protocol. Use only one barrel to scan both sides of the spine, one side at a time. Once a patient has been selected, follow these steps:

Load Patient ID Search Edit Patient New Patient <u>F</u>1 Pre E2 Pat+Post E3 Pat+Pre E4 Scan Utilities <u>F</u>5 Pat+9 E6 Pat+Pre E7 Pat+Post E8 Pat+Pre if Post E9 Pre/Post E10 Comment E11 Change Listing F12 Select Scans NC<u>M</u> <u>S</u>can

1. Bring up the scanning screen by hitting the **S** key or clicking the **Scan** button on the home screen. A blank screen displays.

2. Before starting to scan, mark a starting reference point for the scans. Using a washable marker, draw a horizontal line across the spine as a starting point (remember to carefully palpate for cervical or full spine starting point before drawing the line).

3. Select the Infant Mode by hitting the I key or clicking on the **Infant** button at the upper right corner of the screen. If enabled (Setup) voice prompts will guide you.

4. Always start with the right paraspinal surface first. Place the wheels of the **left** barrel on the **right** paraspinal surface while maintaining the probe tip just above the skin and exactly on the drawn horizontal starting line.

5. Pull the trigger, but do not begin scanning immediately! First, a tone sounds (if sound is enabled) and the software displays a screen prompt reading
Initializing Sensors. Next, a second tone sounds, and the software displays a screen prompt reading Scanning, signaling to begin the scan.

6. Scan upward towards the head with an even cadence while maintaining the left probe tip just off the skin. When the hairline is encountered, gently press the probe down onto the skin to displace the hair. Stop the scan when the occiput is encountered and release the trigger before lifting the scanner off the spine. A screen prompt displays, reading Ready to Scan.

7. Now, place the wheels of the **left** barrel on the **left** paraspinal surface while maintaining the probe tip just above the skin and exactly on the drawn horizontal starting line.

8. Again, pull the trigger and wait for the set of tones or prompts indicating to begin the scan. However, this time **do not stop at the occiput!** Scan just past the termination point of the right paraspinal scan and release the trigger (the computer references the distance of the scan to the starting line and only saves the exact same number of infrared signals as the right paraspinal scan).

Once the left side scan is complete, a thermal plotted graph immediately displays on the screen. Hit the **Esc** key or **Enter** to save the scan.

Unlike scanning adults, infant scan repeatability is dependent upon the scanner's wheel encoder and the **starting point** of the scan. The reference point of each scan is the drawn horizontal starting line. Consequently, the only error involved is the ability to **start** the scan at the same point each time.

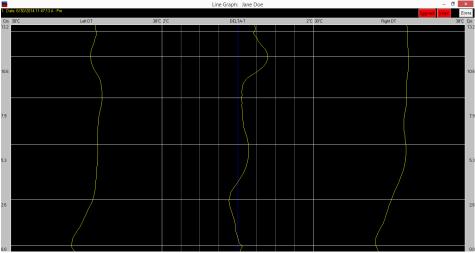
Even if the starting points are not perfect, the Left and Right DT graphs will be an accurate display of any variations or "breaks" from the normal straight line expected.

3.11 Scan Display Screens

These 4 scan display screens are used to view the patient's thermal scans:

3.11.1 Line Graph Screen

This is the most accurate thermal interpretation display. The center line represents the Delta-T (or difference) in temperature from each side of the spine. Any lateral deviation of this line is toward the hotter side of the spine. Each light gray vertical line represents 0.5 degrees C.



The left and right lines represent the DTs or direct (actual) temperatures over the paraspinal skin. Any deviation of these lines to the right represents a hot area over the spine, while left deviations indicate cold areas.

To establish a patient's pathological thermal pattern, at least 2 matching scans must be taken 15 minutes apart during the first office visit. Every deviation of the Delta-T and DT lines must match in location along with Delta-T deviations greater than 0.3 degrees C. Once the thermal pattern is established, each future office visit's scans can be compared to determine the presence of neuropathophysiology. For more information on establishing patterns and interpreting graphs, please reference Dr. William Amalu's book located in the Literature folder on your installation media.

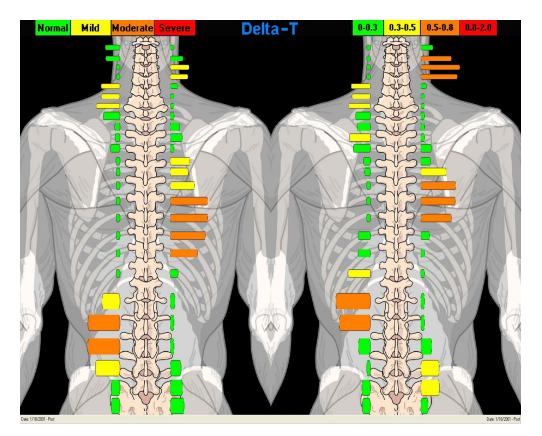
Press the **N** key while in a patient's line graph and a Normal line graph will appear. Next, press the B key to show their bar graph beside a Normal bar graph.

Break Lines may be placed by pressing the **L** key and clicking on the graph. You may place up to 20 Break Lines. Press **L** again to stop placing the lines. Use the **H** key to toggle the display of the lines. Lines may be removed by pressing **L** twice.

3.11.2 Spine Bargraph Screen

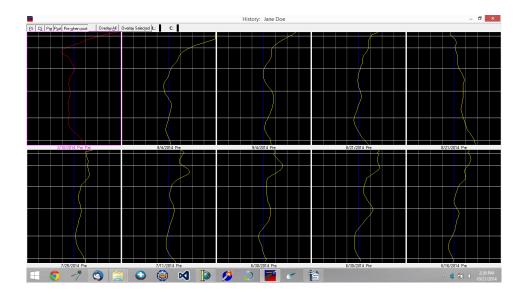
At the line graph screen, hit the B key to toggle between the Line graph screen and the Delta-T spine bar graph screen. This screen simplifies the data in a way that makes it easy for patients to understand. It is not meant to be used as anything other than patient education. To see the DTs (direct or actual temperatures) in this view simply hit the D key to toggle between the Delta-T and DT spine bar graph screens. The A key shows the bar graph with an autonomic chart. If you only see red bars on one side you may need to check Center Bargraph on the SCANS tab in Setup.

If two scans are chosen for viewing, the scans will appear side by side on the screen as shown below.



3.11.3 History Screen

The history screen views the patient's pattern, if selected, in the upper left corner along with the next 9 scans in the patient's file. Depending on the settings, the screen displays both full spine and cervical spine, full spine only, or cervical spine only. To temporarily change the display options while at this screen, select the corresponding filtering buttons located in the upper left corner of the screen (FS, CS, Pre, etc.). Instructions for permanently changing the display options is covered under Setup – Main Tab.



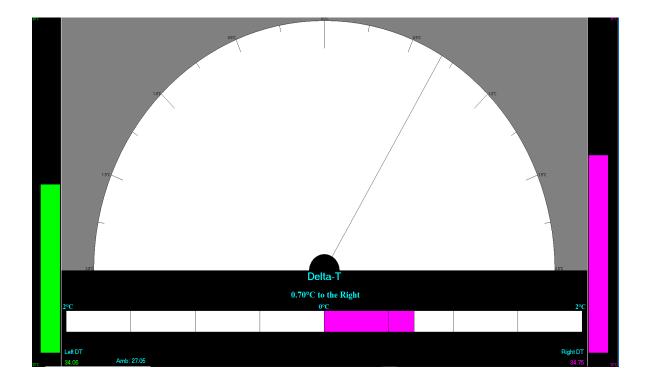
The following functions manage how the scans display on the screen:

- **1.** The Arrow buttons $(\uparrow, \downarrow, \leftarrow, \rightarrow)$ move between scans. The selected scan is highlighted with a border.
- **2.** To view a single scan in detail, double click the scan with the mouse or highlight the scan using the arrow keys and hit the **Enter** key.
- To select more than one scan to view, hit the Spacebar key for each scan to view. Once finished selecting the scans to view, hit the T key or click the Overlay Selected button to view the scans. To view all displayed scans, hit the A key or click the Overlay All button.
- 4. To view more past scans in the patient's database, hit the Page Up and Page Down button.

3.11.4 NCM Screen

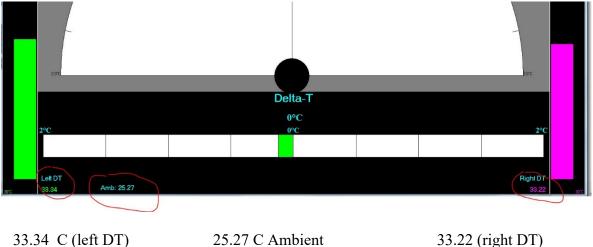
The NCM (neurocalometer) screen is set up to emulate an NCM, Thermometer, or Go-Scope type instrument. The scanner performs in a similar fashion as explained earlier. However, no initiating tones sound. Simply place the scanner wheels on the skin, spacing the probes equally over the center of the spine. Pull the trigger and scan from the lower back towards the head. The computer beeps (if sound is enabled) whenever a spot on the spine reaches 0.5 degrees C Delta-T or more. This pinpoints the exact area on the spine by moving up and down over the area while listening for a set of continuous beeps.

At this point, look at the screen to evaluate the exact magnitude of the Delta-T from



either the meter or digital displays.

If you observe the lower portion of the NCM screen: (after loading a test patient)



33.34 C (left DT) 25.27 C Ambient

Please note the three circled temperatures when you pull the trigger and AIM at the floor (AMB should be around 23 C as well as both Left and Right vertical thermometers. When you AIM under your chin, the Left and Right thermometers should come up to around 33 C.

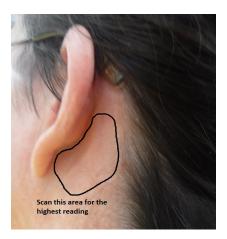
3.12 Mastoid Fossa / Chronometer Readings

Mastoid Fossa or Chronometer readings are always made using the **RIGHT SIDE PROBE ONLY**. Fossa readings are taken after a spinal scan.

1. After a spinal scan is performed, hit the F key, or click the Fossa button in the upper right of the screen. To take a Fossa reading alone, point the scanner into the air, pull the trigger, turn the left probe wheel a few clicks with your hand, and release the trigger. After doing that, press the F key for the Fossa portion of the scan. If voice prompts are selected in Setup (scans Tab) instructions will be given.

2. The NCM screen now displays. Place the **RIGHT PROBE** in the **Right** Mastoid Fossa and pull the trigger. Search the area while watching for the highest temperature reading on the vertical thermometer for the side you are examining. Once a steady clicking is heard, release the trigger. (The clicking sound means that the sensors have reached a state of thermal equilibrium and are ready to take a reading).

3.) Now place the **RIGHT PROBE** in the **Left** Mastoid Fossa and pull the trigger. Again, search the area while watching for the highest temperature reading on the vertical thermometer for the side you are examining and release the trigger. The Delta-T reading displays, referencing the hotter Fossa (i.e. 0.5 °C to the right means the right Fossa is hotter than the left by 0.5 °C).



4. Hit the **Esc** key on the keyboard or pull the trigger to return to the line graph screen. The Fossa reading displays in the upper left corner of the screen with an L or R denoting to which side the reading was hotter.

3.13 Printing Reports

Hitting the **P** key presents you with a pop-up menu for you to select the type of report you want to print:

Lines: This report is a simple printout of the line graphs on the screen

Lines History: This report will produce a simple printout up to 10-line graphs as presented on the screen.

Lines with Narrative: This report is very detailed with regard to the displayed line graph. This level of report can only be printed with a single graph displayed.

Bargraph with Narrative: This report will yield the same results as the lines with narrative selection, but the printout will show a single bar graph instead of a line graph.

Bargraph: This report is a simple printout of a single scan as a bar graph.

3 Bargraphs: This report is a simple printout that will display two bar graphs side-by-side.

10 Bargraphs: This report will produce a simple printout up to 10 bar graphs as presented on the screen.

Utilization: This report printout gives you a one-page utilization review of thermography and the Tytron system. This report may also be used as a medical necessity report.

Info Report: This printout is a very useful general information page that is designed to give patients an understanding of what paraspinal thermography is and how chiropractic works. The amount of data printed out on the reports will depend on the information you typed into the screen you used to enter the patient into the system. The narrative reports contain the highest detail but will contain more information if the fields are filled in on the patient data screen. Simply click on the Edit Patient button and fill out the Patient Settings area if you want this information printed out on the reports.

3.14 The Notes Screen:

Notes: The Notes feature allows you to create, edit, and manage notes of any length. You may also attach files to the notes (x-rays, photos, documents, etc.) Notes are stored in the database linked to the individual patient files. The "Z" key opens the notes screen from most areas of the program.

The Notes		_		Х
Name Attachment Findings JaneDoeFindings.pdf	Jane seems fine.			
+ - 🗸 X C	Attach File Delete File View File S	ave File	Save	Text

3.15 Data Base Maintenance

Database Maintenance is an important step in keeping the Tytron software running smoothly. To load a patient file, the computer must look through the database to find all applicable patient information. Over time the database may become fragmented and slow down as a result of growth from adding new scans and patients. The Tytron uses a very stable and secure database for storing this information. Running the database maintenance reorganizes the information to maintain high reliability and speed.

- 1. Close out of the Tytron Software program
- 2. Click on the File Explorer
- 3. Double click the C3000 folder
- 4. Double click on DBFixer.exe The Database Repair program will open

- 5. Click on Rebuild and Fix All button and wait for the message to read 100% successful
- 6. Exit out of it.
- 7. The Database Maintenance is complete

For optimal scanner performance, complete Database Maintenance on a quarterly basis. Complete database maintenance BEFORE performing a database backup to help ensure a successful backup and restoration process. The Database Maintenance process also repairs potential corruption errors that can occur if the computer "locks up".

🖬 Database Repair 🗕 🗖 🗙
Path: C:\C3000\DB\
Rebuild + Fix All
Encrypt - patients.DB A Encrypt - ROM_Procedures.DB Encrypt - ROM_Tests.DB Encrypt - scans.DB Rebuild complete. 3/1/2019 1:39:30p
Table Status:
Header:
Indexes:
Data:
Rebuild:

3.16 Database Backup

The database backup popup option opens when you close the software. Titronics recommends backing up the software to a removable flash drive at least once a week.

To perform a backup, follow these steps:

- **1.** Close the Tytron Program on all computers on the network.
- 2. On the server, run the Tytron Program and click on the Backup button. (Top Right)
- 3. A pop up box will initiate the backup click Yes
- 4. The Tytron Backup Wizard will ask you where you would like the data saved to
- 5. Click on Browse and locate your Flash Drive. Then click on OK.
- 6. Click Go.

3.17 Database Restoration

If the computer malfunctions, causing damage to the patient database, the Database Restoration process will restore the database back to the point of the last backup.

The Database Restoration process only works if the patient database has been previously backed up!

To perform a restoration, follow these steps:

- 1. Close the Tytron Program on all computers on the network
- 2. Insert the drive that contains the database backup files
- 3. Open the drive containing the backup
- 4. Double click the backup zip (TytronBackupMM-DD-YYYY.zip)
- 5. Go to Home, Select All
- 6. Go to Home, Copy to, Choose location ...
- 7. Locate Drive C and open the C3000 folder and then the DB folder
- 8. Click on the Copy button
- 9. Select Replace the files in the Destination
- 10. Database Restoration is complete
- 11. Run the Tytron Program to verify successful restoration by loading a patient

3.18 Recoup Suite Management

Many offices use post-adjustment Recoup Suites. After an adjustment is delivered, the patient is placed supine on a table for a short time period before a post-adjustment scan is taken. When taking post-adjustment scans on a same-day office visit, a 15-minute time period between pre and post scans is required to follow with strict infrared imaging

protocol. The patient needs this minimum acclimation period in order to eliminate any artifacts left over from the adjustment procedure. Please note that if any type of physical therapy is performed, it is after the post-adjustment scan is taken.

To activate the Recoup Suite function, click the Setup button at the home screen and select the Main tab. At the Recoup Suite area, enter a value (1-300) to display up to 300 recoup suites on the home screen. Entering 0 in this field removes the recoup suite area from the home screen. The recoup suite functionality now displays at the bottom of the home screen.

Once the patient is adjusted, select the patient recoup time and suite. To select the recoup time, click the 15, 20, 30, or 45 Min buttons, or use the corresponding keyboard number as denoted by the underlined number. A pop-up box appears and prompts to choose the suite number. The program automatically selects the next available suite by default, this can be manually changed if it is incorrect. This pop-up box also allows the manual designation of custom recoup times (i.e. 40 minutes). Once the recoup time and suite are selected, hit the Enter key or click the OK button to complete the process.

The patient's name (or initials), suite location, remaining recoup time now appears in the recoup suite area. Once the patient is ready to be removed from recoup, a tone sounds and the suite box to the right flashes. To quickly display this patient for scanning, hit the letter key that corresponds to the patient's name on the list or double click on the patient's name. The patient now displays at the home screen and is ready for scanning. Once the scan is performed, the patient's name is automatically removed from the recoup list. To remove a patient from the recoup suite list, select the patient using their corresponding letter, then click on the 0 Min button.

The Recoup Suite management system gives the busiest of offices the ability to closely monitor every patient while improving patient flow and overtime problems.

3.18.1 Resolving Recoup Suite Issues

It may be necessary to repair the recoup file if the computer encounters an error related to recoup suites. To repair the recoup file, complete the following steps:

1. Close the Tytron Program on all of the computers on the network

2. On the Windows taskbar select File Explorer >This PC >Disk C >C3000 >Fix Recoup

3. A few screens display momentarily on the screen, then the process is complete.

3.19 Export / Import

The import and export functions allow for the transfer of patients between computers. Once exported, a patient's file can be sent on disk or e-mailed to another computer.

Export

With a patient loaded, clicking **Export** displays the dialog box shown below, indicating the number of scans and disk space the export process requires. Click the **Export** button to display the **Save File** screen. Choose the feature to save location and click the button.

Export			
Total scans: 0 Total size: 0K			
Export CSV Export ROM Export All Export Cancel			

Export CVS – allows you to save patient list to a text file to be able to be put into a spread sheet

Export ROM – allows you to sync patient DB to Titronics ROM DB

Export All – allows you to save all patients to a folder

Export – allows you to save individual patient

Import

Click **Import** to display the **Open File** screen. Select the file to import and click **Open**. The dialog below appears, indicating the patients that have been imported to the database. Click **Load File** to select another file or click on **OK** to return to the main screen.

Import
Patients Imported:
Jane Doe - 100570
Load File OK

3.20 Network Setup Instructions

- **1.** Install the Tytron Software on each computer to be networked.
- **2.** Select a computer to be the server (main computer). Perform the following tasks:
 - Open **My Computer**, then open **Drive C**. Right click on the **C3000** folder and select **Properties**.
 - On the **Sharing** tab select **Advanced Sharing** and make sure **Share this folder** is selected.
 - Click on **Permissions** and add **Everyone** with **Full Control**. Click on **OK** to get back to **C3000 Properties**.
 - Click on the Security tab and click on Edit... Add Everyone and give them Full Control.

C3000 Properties ×			
General Sharing Security Customize			
Network File and Folder Sharing C3000 Shared Network Path: \\Blueone\c3000 Share			
Advanced Sharing Set custom permissions, create multiple shares, and set other advanced sharing options.			
Password Protection People must have a user account and password for this computer to access shared folders. To change this setting, use the <u>Network and Sharing Center</u> .			
Close Cancel Apply			

	Advanced Sharing	х
✓ Share this fol	ler	
Settings		
Share name:		
C3000	¥	
Add	Remove	
Limit the num	ber of simultaneous users to: 20	
Permission	s Caching	
	OK Cancel Apply	

Permissions for C3000 ×	C3000 Properties
Share Permissions	General Sharing Security Customize
Group or user names:	Object name: C:\C3000
	Group or user names:
Add <u>R</u> emove	Administratore (RELEGNE) Administratore) > To change permissions, click Edit. Image Edit
Permissions for Everyone Allow Deny	Permissions for Authenticated Users Allow Deny
Full Control	Full control
Read 🗹 🗌	Read & execute List folder contents
	Read V Write V
	For special permissions or advanced settings, Advanced click Advanced.
OK Cancel Apply	Close Cancel Apply

17. F	Permissions	for C3000	×
Security			
Object name: C:	C3000		
<u>G</u> roup or user name	es:		
Everyone			
Authenticated	Users		
SYSTEM & Administrators		(ministratem)	
Users (BLUEC		ininistrators)	
		A <u>d</u> d	<u>R</u> emove
Permissions for Eve	ryone	Allow	Deny
Full control		~	□ ^
Modify		> >	
Read & execute		~	
List folder conten	ts	✓	
Read		~	
L			
	ок	Cancel	Apply

Select Users or Groups	×
Select this object type:	
Users, Groups, or Built-in security principals	Object Types
From this location:	
BLUEONE	Locations
Enter the object names to select (<u>examples</u>): Everyone	Check Names
Advanced OK	Cancel

3. On the client computers, run the Tytron Program and click the **Setup** button. At the **Main** tab, change the **Data Folder** to reflect the location specified as the server. (In this example, \\ServerName\C3000\DB). Note that the **Control Folder** will automatically fill in as you type the path into the **Data Folder**.

Test the network configuration to ensure it is successfully installed

3.21 Periodic Maintenance

(Field Cleaning Procedure)

Titronics recommends periodic maintenance of the Tytron to ensure proper functioning. The scanning barrels collect debris over time that needs to be removed. Debris may cause the Tytron to read incorrectly.

The following are signs that the Tytron may need periodic maintenance:

- The graph shifts to the side.
- The graph swings to the side.
- Unable to reproduce normal graph results.

The following are solutions to ensure the Tytron functions properly:

Light Cleaning

• For small amounts of debris in the barrels, Titronics recommends using canned air (available at most electronics stores). Insert the spray straw approximately 1" into the barrel tip. Spray for three seconds. Allow the unit to sit for 15 minutes.

Heavy Cleaning

• For large amounts of debris in the barrels, Titronics recommends using a cotton swab lightly moistened with water. Insert the moistened cotton swab approximately 1" into the barrel tip. **Do not touch the lenses!** Trap debris along the wall of the barrel and pull debris out. Follow up with the canned air process for any small debris left. Allow the unit to sit for 15 minutes.

• **NO** cleaning chemicals or liquids should be used on the Tytron. This may result in damage to the barrels and lenses.

• Titronics recommends sending in the Tytron for a cleaning and calibration once every three years or when periodic maintenance isn't able to restore Delta T (center) readings to within +/- 1 degree.

• Soapy water may be used to clean the exterior of the scanner (handle and wheels). Using alcohol or other solvents may damage the scanner. Do not submerge the scanner.

4 Safety Instructions

4.1 Safety Information for Devices Intended for Single Use

Not Applicable. The Tytron scanner is not a single use device.

4.2 How to Use the Product Safely

There are no contra-indications to recording a patient's skin temperatures with an infrared thermometer.

Any contact with the patient is by the polycarbonate barrel tips, or the rolling rubber "tires" on the guide wheels. distance odometer.

The only limitation is that for accurate readings, the instrument temperature (outlined in the specifications for the C-5000 thermal scanner) be within the acceptable limits. The exam room should be shall also be monitored and within the specified range. The patient shall acclimate for the specified time period with no external drafts on the body.

The doctor (holding the instrument) will be grounded well if the office wiring is within specification since the instrument is tied to the computer frame which should be grounded through connection to the wall power socket. If the room air is dry, the room is carpeted, and the patient picks up a static charge – the patient may get a slight "tingle" when touching the doctor. This is no more a hazard than the patient touching anything else in the office that may be grounded.

There is no malfunction of the device that would affect the patient's safety. If the office wiring were compromised and the power supply "neutral" connected to the computer and the computer chassis from the wall socket was at a potential other than "ground" the doctor could be exposed to possible shock, as would anyone touching anything connected to that socket.

It is the responsibility of the office personal to maintain the cleanliness of the barrel tips and rolling wheels after each use of the instrument. The doctor / technician performing the thermal scan must do so on bare skin. The measuring wheels must contact the skin while the scanner is glided from S1 or T1 to the occipital shelf. As the scanner approaches the hair line, the barrel tips contact the skin to push the hair that may be there forward and against the skin for good thermal contact and IR emission to the sensors. All living skin have normal microbiological flora; our pH balance keeps these microorganisms in check. Defects in the patient's defense mechanism increase the risk of infection caused by specific groups of microorganisms that might be transmitted from the previous patient scanned via the scanners rolling wheels or barrel tips.

The use of a germicidal disposable wipe is an excellent tool to minimize the risk of patient to patient or doctor to patient contamination. An intermediate level disinfectant such as the product Super Sani-Cloth (a premoistened wipe designed to be compatible with nonporous surfaces and equipment made of plastic, rubber, aluminum and more.) is an excellent tool with which to "wipe" down the scanner barrel tips, wheels, and handle. Medical offices perform wipes of equipment and surfaces that will come in contact with patients. Most offices will do a thorough "clean down" at the end of the day and would

have some form of a disinfectant wipe such as the Sani-Cloth available. A quick "wipe" of the barrels and wheels after each patient would easily allow 2-minute contact time against enveloped/ non-enveloped viruses, bacteria, TB, fungi, multi-drug resistant organisms and bloodborne pathogens to be destroyed. This product meets CDC, OSHA and CMS Tag F441 Guidelines as an effective disinfectant. EPA Reg. No. 9480-4. This information is made available to the doctors.

PRODUCT DESCRIPTION

Super Sani-Cloth® Germicidal Disposable Wipe is a premoistened nonwoven durable wipe containing a quaternary/alcohol based solution. Recommended for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Designed to be compatible with hard nonporous surfaces and equipment made of stainless steel, plastic, Formica® laminate, glass and more. Some organisms are removed from the surface by thoroughly wiping the surface with the wipe. Most remaining organisms are killed within two (2) minutes by exposure to the liquid in the wipe.

CHEMICAL COMPOSITION

Active Ingredients:

n-Alkyl (68% C12, 32% C16) dimethyl ethylbenzyl ammonium chlorides	0.25%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	
Isopropyl Alcohol	
Other ingredients.	
TOTAL	
Each cloth is saturated with 5,000 parts per million of active guaternary ammonium chlorides.	

4.2.1 Instrument Protection

The metal case of the instrument coupled with the shielded USB cable provides excellent protection from any procedures in the area that may be emitting electromagnetic interference. The C-5000 has passed all standards for any emissions that would interfere with other equipment (see Appendix).

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in serious injury or death.

4.2.2 Technical Life Span Seven+ years, limited only by insufficient care.

4.2.3 Safety information related to the intended use and reasonably foreseeable misuse;

The Undesired Events (Hazards) :

Any flaw in the optics, electronics, or software that would alter the reproducibility of the graphing function would be an undesired event.

Optics -1 - Blockage of the IR RADIATION from the patient reaching the IR sensor.

2 – Degradation or failure of the IR sensor

 $Electronics-1\ \text{-}\ Failure\ of\ any\ of\ the\ micro-electronics\ (amplifiers,\ processor,\ etc.$

2 - Communication IC's, cables, power supply.

3 – Error in coding, failure of any purchased software subroutines.

Obvious failures in any of the above are indicated in the data display graph screens. While actual temperatures are displayed, the "shape" of the temperature trace along the spine is of greater interest to the examiner. The displayed trace after a "scan" shall have a continuous, smooth appearance with a consistent length from one scan to next. Each trace (Left, Differential, Right temperature traces) should display within the provided "box" on the computer screen. That is between 30 and 38 degrees C for the Left and Right actual temperature readings and +/- 2 degrees C. for the differential or Delta display. Any dis-continuity in the trace would indicate a reading or transmission error and is an obvious alert to the person performing the scan.

Patient Skin Contamination:

There are two materials that touch the patient: The distance measuring wheels are an elastomeric "rubber" formulation that is bio compatible. The polycarbonate clear tips on the focusing barrels are also bio compatible. The finish on the scanner is a Polyester Polyurethane baked on coating (powder coat trade name) that is also bio compatible. The concern for skin contamination is in the possible transfer of any infectious microorganisms between patients. The barrel tips sometimes contact the skin in finishing the cervical scan, the measuring wheels are in constant contact during the 3-6 second rolling scan of the patients back.

Rolling Scan of the Patient's Back:

The use of a germicidal disposable wipe is an excellent source to minimize the risk of patient to patient or doctor to patient contamination.

4.2.4 Personal protective Equipment

The examiner should follow the established procedures in the office for protective equipment, this may include protective gloves when examining a patient with skin disorders, followed by disinfecting the contact areas barrel tips and rolling wheels on the instrument.

4.2.5 Product limitations and restrictions:

The only limitations are on the environment temperature in which the patient is being examined. Following the guidelines in the Appendix is recommended.

4.2.6 Installation safety information:

The instrument draws its power from the USB port on the host computer as well as it's ground reference (instrument handle). It is the responsibility of the installer to ensure that the building wiring, specifically the wall socket the computer is connected to is wired properly

4.2.7 Safety information when using the device in combination with other devices: The only other device used with the instrument is the host computer, this is covered in the previous section under installation.

4.2.8 Maintenance safety information:

The only maintenance required is that of removing any debris or dust that may accumulate in the barrels, blocking the infrared emission from the body from reaching the sensor. This would reduce the temperature readings but could not harm the patient. The examiner would be aware (see "Scanner Calibration Questions" in the Appendix) and would follow the barrel / lens cleaning procedures indicated.

4.2.9 Safe Disposal:

There are no hazardous substances in the C-5000 instrument, We recommend recycling the aluminum handle and head if possible.

4.3 Graphical Symbols

inci Explanation of Staphical systemotic		
Symbol	Meaning	
Degrees C. (°C)	Degrees Centigrade	
Degrees F. (°F)	Degrees Fahrenheit	
cm, mm	Centimeters, Millimeters	
СЕ	Committee of Europe	

4.3.1 Explanation of graphical sysmbols

4.4 Potential health consequences:

There are no potential health consequences in the use of the instrument as all exposed surfaces have passes all standards for skin contact. (ASTM F719 - 81(2012) Cross contamination from one person's skin through contact with the rolling wheels or measuring barrel polycarbonate tips to another is possible. Preventing this by following office procedures for disaffecting surfaces that patients contact is the responsibility of the office personal. Instructions for cleaning the Instrument are

There are two materials that touch the patient: The distance measuring wheels are an elastomeric "rubber" formulation that is bio compatible. The polycarbonate clear tips on the focusing barrels are also bio compatible. The finish on the scanner is a Polyester Polyurethane baked on coating (powder coat trade name) that is also bio compatible. The concern for skin contamination is in the possible transfer of any infectious microorganisms between patients. The barrel tips sometimes contact the skin in finishing the cervical scan, the measuring wheels are in constant contact during the 3-6 second rolling scan of the patients back.

The use of a germicidal disposable wipe is an excellent to minimize the risk of patient to patient or doctor to patient contamination. An intermediate level disinfectant wipe (a premoistened wipe designed to be compatible with nonporous surfaces and equipment made of plastic, rubber, aluminum and more.) is an excellent tool with which to "wipe" down the scanner barrel tips, wheels, and handle. Medical offices perform wipes of equipment and surfaces that will come in contact with patients. Most offices will do a thorough "clean down" at the end of the day. A quick "wipe" of the barrels and wheels after each patient would easily allow 2-minute contact time against enveloped/ non-enveloped viruses, bacteria, TB, fungi, multi-drug resistant organisms and bloodborne pathogens to be destroyed.

4.5 Personal Protective Equipment

The examiner should follow the established procedures in the office for protective equipment, this may include protective gloves when examining a patient with skin disorders, followed by disinfecting the contact areas barrel tips and rolling wheels on the instrument.

4.6 Process Overflow - N/A

5 Packaging

5.1 Transport and Store the Product

Keeping the storage case and instrument from coming in contact with any corrosive liquids is critical (saltwater for example). Conductive liquids could reach the circuit boards and damage them. Short periods of contact (less than 2 hours) to saltwater may be taken care of by flushing the scanner with warm clean water. If any moisture finds its way between the Fresnel lenses and the sensors (inside the barrels) the scanner will have to be returned to the factory or authorized dealer for servicing.

5.1.1 Packaging Dimensions

The shipping case: **SPECIFICATIONS** –

SKU(s)	69318, 62271	Color	Black
Brand	Voyager	Material	Aluminum
Product Height	6 in.	Product Length	18 in.
Product Weight	5.8 Lbs.	Product Width	13 in.
Shipping Weight	5.60 Lbs.	Size(s)	18 in. x 6 in. x 13 in.

Weight with scanner, base, manual, and cables is 10 pounds (4.5 Kilograms) Composite wood material is compliant with CARB 93210 Phase 2 Placement of scanner in the Voyager shipping case:





5.1.2 Lifting, handing and transporting the product

To lift the product safely:

At less than 5 KG, the instrument and case are within safe limits for lifting by most adults.

To handle the product safely:

Handle with care as you would with any fragile instrument (camera, glass ware, etc.) **To transport the product safely:**

Package the instrument as shown on the previous page, place the instrument case in a heavy-duty corrugated constructed cardboard box with a minimum of one inch (2.5 co) packing beads around all 6 sides.

5.1.3 Storing the product

The Tytron Instrument is best stored in the original case sitting, on the top layer of protective foam. The base, USB cables, and other accessories are kept in the bottom of the box.

The instrument does not have any materials that would be affected by aging over its published Life Cycle (LC) of 7 years, if kept between -10 C and 40 C.

Our Life Cycle Analysis (LCA) over 25 years has shown no degradation of performance as long as the instruments were not exposed to a harsh saltwater environment (submerged in sea water). A relative humidity of less than 60% is recommended for long term storage (> 30 days).

The storage temperature should be between -10 C to 40 C and RH less than 60%.

5.1.4 Storing the product during intervals in normal use

It is best to place the Tytron C-5000 temperature scanner on its heavy aluminum base (barrels facing down) to secure it from slipping off a desk or shelf. More importantly this

position minimizes any air borne dust particles from entering the open ends of the barrels and "blocking" the IR emissions from reaching the sensors.

If left over night in an office that has automatic temperature control, allow sufficient time before use for the instrument to return to it's operating temperature range (21 c to 25C) before use if the room is being warmed or cooled after opening the office.

5.1.5 Securing the product against shocks

The ASTM D 4169 standard has been addressed in the area of vibration. The concern is in the event of a high shock where the instrument is dropped from greater than 1 meter onto a solid, immoveable surface (a concrete floor). The instrument is designed to protect itself by absorbing some of the energy by shearing 4 nylon 6-32 screws that hold the "head" to the "handle". The head and handle are the two most heavy components that will experience a high de-acceleration when dropped. By allowing the screws to "shear" and absorb the shock, the polycarbonate tips of the barrels are better protected from damage. These plastic screws can be replaced by the user.

To secure the product against shocks:

- 1. Place the instrument between the foam pads in its original case when not in use, make sure the Aluminum base is below the lower pad (isolated from the scanner).
- 2. If shipping the case, place it in a heavy-duty corrugated constructed cardboard box with a minimum of one inch (2.5 co) packing beads around all 6 sides.

5.2 How to Install the Product

5.2.1 There are no restraints to remove –

The carrying case will lift out of the shipping box.

5.2.2 Un Packing the Tytron Scanner

Open the protective metal foam lined carrying case, remove the Tytron scanner and confirm the contents listed in 5.5.3 below.

5.2.3 Packaging contents

- Tytron Scanner (5xxxx)
- 2 USB Cables
- Tytron Scanner Holder
- Tytron Software Installation Media (Includes Calibration File, Drivers, Manual, Clinical Interpretation Book, Articles and Poster)
- Repair Kit

5.2.4 Verification of the product

The Tytron scanner is indicated for use in detecting, measuring, recording, and graphing the skin temperature on both sides of the spine of adults and children by chiropractors and other health care professionals. It is to be used before and after therapy is rendered as part of monitoring the patient's response to care, similar to a common thermometer.

5.2.5 Minimum space needed

The resting position of the scanner between scanning patients should be away from any heat sources, cooling vents, open windows that might allow an uneven heating or cooling air currents or sun light to alter the homogeneous scanner "head" temperature.

5.2.6 Interconnection diagram

The instrument connects via a standard USB AB Cable:



There are no tools required for the installation of the product.

5.2.10 Installation of protective features

The only protective device would be a soft pad in the area of use for the scanner, should it be dropped to protect the scanner itself from breakage.

5.3 How to Commission the Product

All living skin have normal microbiological flora; our pH balance keeps these microorganisms in check. Defects in the patient's defense mechanism increase the risk of infection caused by specific groups of microorganisms that might be transmitted from the previous patient scanned via the scanners rolling wheels or barrel tips. The use of a germicidal disposable wipe is an excellent tool to minimize the risk of patient to patient or doctor to patient contamination. An intermediate level disinfectant such as the product Super Sani-Cloth (a premoistened wipe designed to be compatible with nonporous surfaces and equipment made of plastic, rubber, aluminum and more.) is an excellent tool with which to "wipe" down the scanner barrel tips, wheels, and handle. Medical offices perform wipes of equipment and surfaces that will come in contact with patients. Most offices will do a thorough "clean down" at the end of the day and would have some form of a disinfectant wipe such as the Sani-Cloth available. A quick "wipe" of the barrels and wheels after each patient would easily allow 2-minute contact time against enveloped/ non-enveloped viruses, bacteria, TB, fungi, multi-drug resistant organisms and bloodborne pathogens to be destroyed. This product meets CDC, OSHA and CMS Tag F441 Guidelines as an effective disinfectant. EPA Reg. No. 9480-4.

5.3.1 Installation of the software

Follow the "Tytron C-5000 Fast Setup" instructions in section **2.10** Tytron C-5000 FAST SETUP

Double click on the Tytron Icon on the Windows home screen to launch the program. Click on Setup and enter the registration number supplied with the Flash 'Drive. Connect the scanner, the driver will be downloaded automatically from the internet, click on

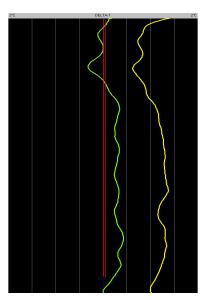


the 4th tab (scanner) and verify on line 1 – Scanner Detected , pull the trigger and verify "Trigger Pulled" message complete.

Setup for Tytron C-3000 v2.2.1.15	×
Main Scans Printing Scanner 👉	Connect to Support
	canner Settings
Scale Factor 0: 1052 Offset 0: 3 Detected scanner #51375	
Offset 1: 200 Trigger Pulled cause probl	
Scale Factor 2: 1007 Offset 2: 4 Timeout(see	le recievers. conds): 3

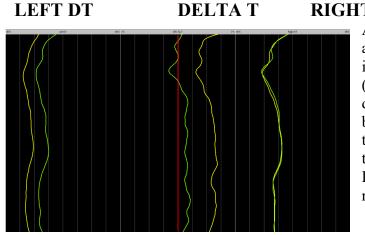
Hit the Escape key to return to the C-3000 home screen. Click on "Quick Scan" and perform a scan to verify the installation is complete and the scanner is functioning.

5.3.2 Calibration check and <u>cleaning procedure for the C-5000</u>



We are sometimes asked the question how often my scanner needs to be calibrated. The best way to answer this is to monitor the CENTER LINE GRAPH scans. If most of the scans you take every day appear to be moving "OFF CENTER" (like the YELLOW line) by more than one or one and a half degrees C. (three of the white lines) *and* you have followed the cleaning procedure outlined in the <u>www.titronics.com</u> video and below, it is an appropriate time to allow us to replace the lenses and perform an "in house" precision calibration. The Fresnel Lens and focusing barrel used in the Tytron scanners is one of the key elements that separates the Tytron's from all other chiropractic graphing instruments in accuracy and specificity.

The microscopic groves that make this type of lens so perfect for infrared measurements may fill over time with microscopic "dust" that can't be "blown" out. That is why lens replacement and recalibration may be required at some point.



RIGHT DT

As can be seen in this example a scan made with a calibrated instrument is centered (GREEN) compared to a scan done with "dust" in the left barrel (YELLOW) – reducing the LEFT DT temperature and there by shifting the center DELTA T line graph to the right.

Inspection and

Cleaning of the Barrels and Lenses

Weekly inspection of the barrel cavities is an excellent idea and should be part of your operating procedures for maintaining the inherit accuracy of your scanner.

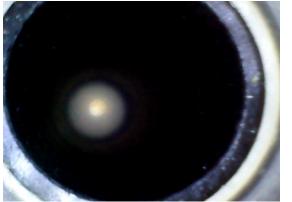
Sample images of Tytron barrels on a scanner needing to be cleaned:

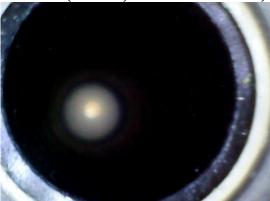




Right barrel as received Left Barrel as received A DRY Q-TIP CAN "FLICK" OUT ALL THE MATERIAL ON THE **BARREL WALLS!**

(Do not insert the Q-Tip more than 1.5 inches (3.8 cm) into the barrels.)





Left Barrel after dry Q-Tip cleaning Right Barrel after dry Q-tip cleaning



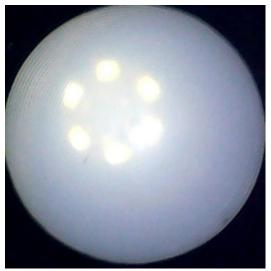
Left Lens as received



Right Lens as received



Left Lens after air blast



Right Lens after air blast

The Dust-Off air cans come with a plastic "nozzle" that will allow you to direct the blast to within 3.8 cm of the lens, directly at the groves in the lens, removing any debris.

5.3.3 Sterilization of the scanner is not required of the product before use

A disinfectant such as the product Super Sani-Cloth, is an excellent tool with which to "wipe" down the scanner barrel tips, wheels, and handle. Medical offices perform wipes of equipment and surfaces that will come in contact with patients.

A Closer Look at the Lenses at the base of the Barrels

6 **OPERATION/USE**

The correct scanning procedure is demonstrated on videos available on the Titronics Research & Development website (www,titronics,com). When performing a scan, it must be done on bare skin (not through clothes) starting at the sacrum and rolling up to the occiput. The stopping point is the contact of the barrel tips to the occipital shelf. This is the reference point that is used to align graphs that are to be compared. The imaging room should conform to the thermodynamic attributes required in thermal image acquisition. The temperature of the room should be such that the patient's physiology is not altered to the point of shivering or perspiring. The ideal temperature range is between 18 and 23 degrees C. The examining room must have an ambient temperature thermometer to accurately monitor the temperature of the room.

- Instructions to be given to the patient prior to the examination:
- No sunbathing of the area to be imaged 5 days prior to the exam.
- No lotions, creams, oils, powders on the area to be imagined the day of the exam.
- No showering closer than 1 hour before the exam.
- No physical therapy, EMS, TENS, ultrasound treatment, acupuncture, chiropractic, physical stimulation, sauna, or steam room use, hot or cold pack use for 24 hours before the exam.

6.1 Verification of Correct Installation and Use of the C-5000

After following the software and hardware installation outlined in section 2.10, perform scans on several individuals. Compare repeated scans on the same person to and verify that the graphing lines fall within their individual boxes (Left DT, Delta T, and Right DT). As the technician performing the scans practices this, the scans should fall right on top of each other when overlaid (function F5 screen – Pat + 9).

The maintenance required is to keep the barrels free of dead skin (near the tips) and any accumulated dust.

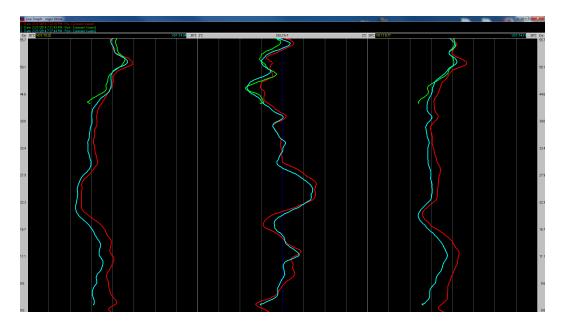
A disinfectant wipe of the rubber tires on the wheels and barrel tips is suggested daily or on any occasions that the doctor / examiner feels necessary.

The rubber tires can be replaced should they become worn or difficult to clean well. There are spares in the "Repair Kit", more can be ordered online (www.titronics.com). See section 5.3.2 for calibration checks. When the Delta-T (center) line graph remains more than 1 degree off to the left or right of center after following the cleaning procedures the scanner should be returned to Titronics R&D or a qualified repair / calibration center'

6.2 Verification of correct maintenance

To verify correct maintenance:

Perform several full spine and cervical graphs on a test patient. Over lay these scans):



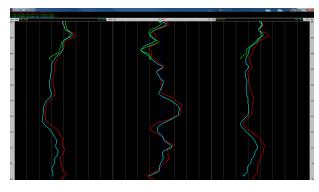
If the examiner performed the scanning accurately, ending at the occipital shelf, the overlaid scans should appear as they do in the above graph. The average center graph (Delta-T) should be centered in the Delta-T "box". This is a perfect field test of the instrument's calibration and maintenance.

The distance measuring function is tested using a meter stick or other ruler to layout a path on a flat surface of at least 50 - 75 cm. Scan this "course" several times and confirm the distance readings on the scanning screen.

6.3 Identification and replacement of consumable components

The only consumable that the operator can replace is the rubber "tires" on the guide wheels. They can be "rolled off" the rim and easily "rolled" back on. The rubber tires can be replaced should they become worn or difficult to clean well. There are spares in the "Repair Kit" and more can be ordered online at <u>www.titronics.com</u>.

6.4 Verification of correct calibration of the device – follow procedure outlined in 6.1.1



If the center graph isn't "centered" follow the cleaning instructions in section 2.3.2.

If this doesn't bring balance back to the average center graph scans, **a factory calibration will be required**. The Fresnel lenses will be replaced, and the instrument will be brought to a stable temperature in a temperature controlled room and calibrated against

a room temperature "black body" and a precision 36.0 degree C "Black Body". The temperature monitoring instruments are checked annually to meet ISO/IEC 17025, ANSI/NCSL Z540-1, and 9001 standards.

6.5 To calibrate the product:

The instrument must be returned to the factory for calibration if cleaning the barrels and lenses as described in section 2.3.2 doesn't restore balance.

6.6 Verification of sterilization:

The C-5000 does not require sterilization, it may follow the same general cleaning maintenance as other office devices that are not used in surgery.

6.7 How to Use the Product

6.7.1 Treatment of vulnerable people

There are no materials or substances involved in the use of the C-5000 that would in any way effect children, pregnant or breastfeeding women or treatment of other patient groups.

6.7.2 Operational environment

The temperature of the exam room shall be between 18 and 23 degrees C., the humidity of the room shall be controlled such that there is no moisture build-up on the skin, perspiration, or vapor levels that can interact with radiant infrared energy. The exam room should have an ambient temperature thermometer. Room shall be free from drafts, heat and air conditioning sources must be minimized in the room and be kept well away from the patient.

6.7.3 Using the device in combination with other devices

The C-5000 is connected to a computer via a standard AB USB cable. The host computer will need a Windows Operating System, or a Mac with a parallels APP that can run Windows software. 4GB ram and 500gb storage and at least a 720p display is minimal. 1080p is better. If the host computer is wall powered, it should have a 3 prong plug and be grounded.

6.7.4 The C-5000 does not emit any radiation and complies with emitting hazardous radiation:

Compliance Statement

Device Name: TyTron

The responsible party for the compliance of this device is:

Model Number: C-3000

Titronics Research & Development Co. 400 Stephans Street, Suite D PO Box 470 Tiffin, IA, 52340-0470 USA (319) 545-7377

FDA: Trade Name: Regulatory Product Code: Dated: Received: K974208 TyTron C-3000 Class: II HCS October 28, 1997 November 10, 1997



CAUTION:

Failure to comply with the user guide instructions can result in personal injury, fire, or other Consequences.

FCC Digital Emissions Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency and if not installed and used in accordance with the instructions, may cause harmful interference of radio communications. However there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the equipment.
- Connect the equipment into an outlet on a circuit different from that of the affected equipment.
- Consult the manufacturer for help.

Operation is subject to the following conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation.

Canadian Digital Apparatus Compliance

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.

6.7.5 Manual operation

The C-5000 must be used with a computer. The only control on the instrument is the "Trigger" which, when depressed connects the scanner to the computer as long as it is depressed. All other operations are controlled from the computer keyboard or touch screen.

6.7.6 Measuring function

The main indication of use is to allow the doctor or examiner to view the temperature balance from one side of the spine to the other and the "straightness" of the line graphs from sacrum to occiput. It is the SHAPE of these lines that is of interest NOT the absolute temperature. Deviations or departures from an otherwise fairly straight line graph are of interest to the doctor, While actual temperatures are displayed, their value or degree of difference (Left to Right) or the amount of "break" off the Left or Right temperature graph lines is not important, only that they vary from scan to scan within a narrow band (< 0.5 C).

Classification:FDA - Class II (USA)CE - Class I – Measuring (Europe)Model:TyTronSpecifications:Displayed Temperatures Accuracy+/- 1degree CSeries:C-5000Differential 0.1 degree C resolution DistanceOdometer +/-0.25 CMOdometer +/-0.25 CM

6.7.7 Starting/Stopping the product's operation



The software is opened by clicking the mouse on the host computer's screen over the symbol. The software is "closed" by returning to the "C-3000 Home screen and right screen) $-\Box$ ∇ clicking on the X (upper

6.7.8 Checks before using the product

The operator may click on Quick Scan and perform a test scan under his chin on himself.

6.8 In Emergency and Exceptional Situations

The user or patient may report to the manufacturer or competent authority of the member state any serious incident that may occur in relationship to the use of the C-5000. If in the EU, report is to be made to the member state in which the user/or patient is established.

6.8.1 Emergency Situation

In case of an emergency situation:

The user or patient should follow the procedures established in the office in which the exam is being performed. In the USA it would normally be to alert the professional staff/ doctors immediately and **call 911** for emergency medical help.

7 7 MAINTENANCE

See the maintenance instructions – section XXX for both non-qualified and qualified trained person.

7.1 Reusing the Device; Cleaning the device

The C-5000 is intended to be used (like a forehead thermometer) over and over again on patients. Like any device that touches the patient's skin, the barrel tips and wheels may be disinfected. The use of a germicidal disposable wipe is an excellent tool to minimize the risk of patient to patient or doctor to patient contamination. An intermediate level disinfectant such as the product Super Sani-Cloth (a premoistened wipe designed to be compatible with nonporous surfaces and equipment made of plastic, rubber, aluminum and more.) is an excellent tool with which to "wipe" down the scanner barrel tips, wheels, and handle. Medical offices perform wipes of equipment and surfaces that will come in contact with patients. Most offices will do a thorough "clean down" at the end of the day and would have some form of a disinfectant wipe such as the Sani-Cloth available. A quick "wipe" of the barrels and wheels after each patient would easily allow 2-minute contact time against enveloped/ non-enveloped viruses, bacteria, TB, fungi, multi-drug resistant organisms and bloodborne pathogens to be destroyed. This product meets CDC, OSHA and CMS Tag F441 Guidelines as an effective disinfectant. EPA Reg. No. 9480-4. The rubber wheels may be replaced if they become de-graded, the barrels and lenses may be cleaned as outlined in section 5.3.2.

Any buildup of dead skin accumulation on the clear polycarbonate barrel "tips" may be cleaned with a Q-tip and warm soapy water.

If the C-5000 is dropped and damaged, it must be checked, re-conditioned, and calibrated by the manufacturer - Titronics R&D - 400 Stephans St. Unit D, Tiffin, Iowa 52340 – USA.

7.1.1 Disinfection of the device

The use of a germicidal disposable wipe is an excellent tool to minimize the risk of patient to patient or doctor to patient contamination. Wipe down the scanner barrel tips, wheels, and handle.

7.2 How to Maintain the Product

7.2.1 Product maintenance by non-skilled persons

If the operator that is performing the thermal scans is unable to create a graph, they are to contact the office doctor or office manager. A call or e-mail to Titronics R&D may be indicated if the technical person in the office is unable to resolve the issue.

7.2.2 Product maintenance by skilled persons

Any maintenance beyond cleaning shall be done by Titronics R&D or an authorized distributor.

7.3 How to Inspect the Product

7.3.1 Weekly inspection tasks

Task	Action
Barrels – check for dust / dead skin	Use Q-tip to remove debris
Lenses – use small flashlight to inspect	Follow cleaning procedure 5.3.2
Wheels – look at hub – axel interface	clean tires, remove any tangled hair
USB Cable	Replace if worn / distorted
Backup the SCANS data	Follow instructions page 50

7.3.2 Monthly Inspection tasks

Task	Action
Calibration Check, review recent scans	If the majority of the center graphs are not centered – advise technician / doctor
Check barrel tips for any damage	Advise technician / doctor
Alternate backup media	Keep one copy off premise

The operator performing the scans should always pay attention to the line graph screens. Any lines approaching the "boarders" of their boxes should be of concern and the troubleshooting (section 8) guides should be followed.

8 TROUBLESHOOTING AND REPAIR

When following the barrel cleaning procedure outlined in 5.3.2, wear eye protection as debris exiting the front of the barrel may be blown toward your face.

If there is a problem with the graphs re-check the calibration and cleaning procedure in 5.3.2. If scanner does not respond to a trigger pull to start a scan, contact the technician / doctor in charge.

Error	Cause	Solution	
Scan does not start when trigger is pulled	USB cord not fully seated	Check and re-seat	
Scan does not start when trigger is pulled	Check in Setup that correct registration number is entered in Main Tab.	Contact technician for correct registration number	
Scan does not start when trigger is pulled	Check function of USB port by using a different USB port on the computer	Check in Device Manager / Universal Serial Bus Controllers for Tytron C- 5000 listing – no errors	
Scan does not start when trigger is pulled	does the white LED glow (next to STATUS) on the handle?	Check power at USB port and cable – if other devices operate – scanner needs repair – inform technician	
Scan does not start when trigger is pulled	white LED indicates power	scanner needs repair – inform technician	
Scan screen comes up on trigger pull, but no graph starts	communication failure	Check cable – if other devices operate – scanner needs repair – inform technician	
Graphs are not within their specified boxes on the scan screen	Scanner / room temperatures not within required standards	Monitor room temperature and ensure patient has acclimated to room temperature.	
Graphs are not within their specified boxes on the scan screen	look for dust / dead skin in barrels blocking IR to lenses	Follow cleaning procedures in section 5.3.2	

8.1 Troubleshooting and repair by non-skilled persons

Graphs are not within their specified boxes on the scan screen		Return patient to waiting room for additional time
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8.2 Troubleshooting and repair by skilled persons - Only trained and qualified personnel may do this, or the warranty is void.

Error	Cause	Solution
Graphs (either left, right, or both are "pegged" hot	connection was lost between the "head" and handle Scanner was dropped and connection was lost	See instructions (for qualified technician) in Appendix for the procedure to restore connection to "head" sensors
scanner head separated from handle – wires are still connected	scanner was dropped, nylon screws sheared, protecting the barrel tips from damage	technician follows procedure in appendix to replace broken screws
scanner head separated from handle – wires have been broken / disconnected	scanner was dropped, nylon screws sheared, protecting the barrel tips from damage	Contact factory for instructions to return scanner for repair
wheels fail to turn easily	Hair / dirt caught around axel	Remove whatever is causing
trigger pulled – no LED light in handle but USB port has power	Trigger switch failure	technician follows procedure in appendix to replace trigger
cleaning procedures fail to restore balance to graphs when viewing a constant temperature black body target at 36 C.	Lens replacement	technician follows procedure in appendix to replace lenses
Barrel tip(s) damaged	Barrel replacement	technician follows procedure in appendix to replace lenses, must be replaced in pairs

USB port ok, LED lights in	Internal processor failure	Contact factory for
handle – still no	or communication IC	instructions to return
communication	failure	scanner for repair

8.3 Repairing a damaged scanner

8.3.1 Tools

The following tools are needed for reparation tasks:

Task	Tools
1. Replace barrels and lenses	Tool 1 - 7/64 th Allen Wrench Tool 2 - 0.050" Allen Wrench
2. Replacing scanner lenses	Tool 1 - 7/64 th Allen Wrench Tool 2 - 0.050" Allen Wrench
3. Replacing scanner trigger	Tool 1 - 7/64 th Allen Wrench Tool 2 - 0.050" Allen Wrench
4. Replacing trigger switch assembly	Tool 3 – 3/32" Allen Wrench
5. Replacing scanner wheels	Tool 2 - 0.050" Allen Wrench

8.3.2 Equipment

The following equipment is needed for reparation tasks:

Only the Allen wrenches in section 3.5.1.1

8.3.3 Materials

The following materials are needed for reparation tasks:

Task	Tools
Task 1 and Task 2	New barrel set with lenses
Task 3	Spacer, spring, trigger, two 4-40 set screws
Task 4	Switch assembly
Task 5	Left and right wheel assemblies

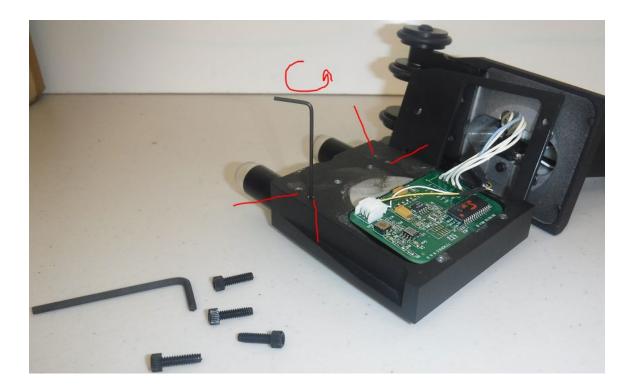
8.4 Repair Instructions

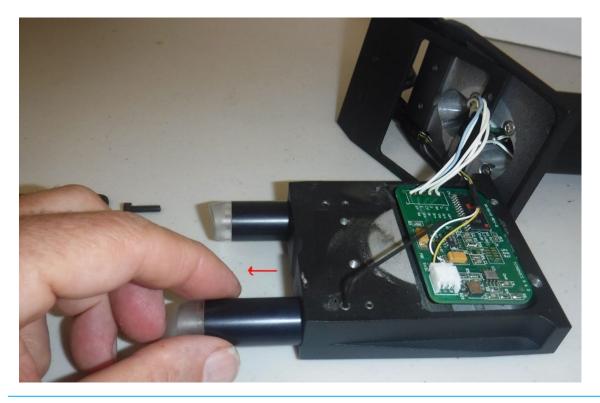
8.4.1 Barrels

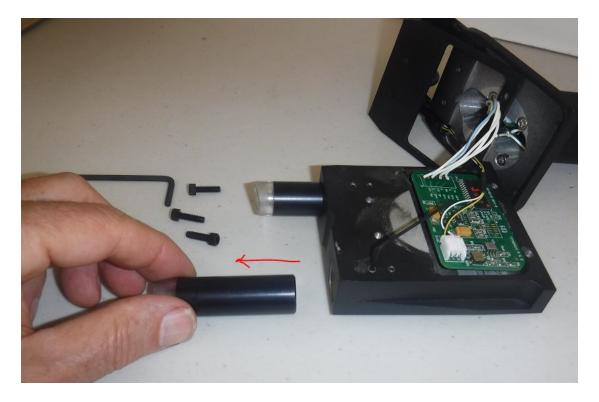
Replacing the Tytron Scanner Barrels

Required tool - 7/64th Allen Wrench – remove 4 plastic screws holding handle to head Required tool - 0.050" Allen Wrench to "loosen" the 4-40 set screws securing barrels









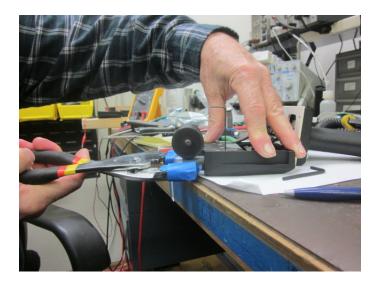
The small 4-40 Allen set screws may be very tight - use the short end of the Allen wrench and make sure it is in all the way before you try to loosen them - just enough to free the barrel - pull straight out (turning may cause the barrel to bind.

8.4.2 Lenses

Replacing Lenses in the Tytron Scanners

The barrels are held in the scanner head with two 4-40 size Allen set screws

The 0.050" Allen wrench (included in the kit) will allow you to loosen the set screws enough for you to remove the barrels. Sometimes the barrel fit requires the use of an adjustable wrench to "encourage" them to come out.



The JAWS of the wrench should be well protected so they don't mar the barrels. If the barrel won't come out with reasonable force DO NOT PROCEED - send the scanner to us.

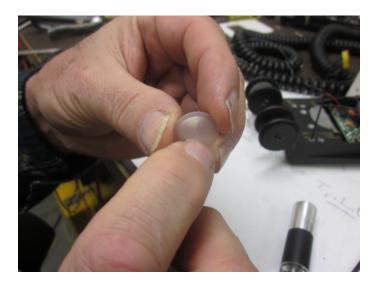
When the barrel does come out, use a nail file to smooth over the spot (dimple) on the barrel body created by the set screw so it will go back in easily.



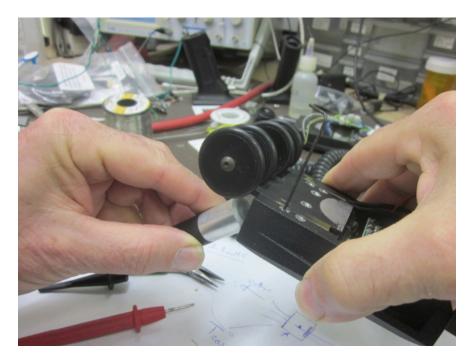
If a lens change is required (only if the lens is filled with dust that won't blow out and your scans are reading "cold"), remove the old lens using a sharp object (like a dentist pick) to pierce it and pull it out.

The lens is called a FRESNEL lens - it has one smooth side and the other side has a series of raised circular ridges that form a "compressed" convex

lens. These ridges can be felt with your fingernail - they are to FACE OUT towards the front of the barrel.



I find the best way to insert the lens is to place it on the back of the barrel (groves facing front) and at a 45-degree angle encourage it to enter the head using the barrel to guide it in. Watch to see that it doesn't do a FLIP on its way into full position. If it does flip - the groves will face the wrong way and the IR output will be weak.



8.4.3 Replacing the scanner trigger

Trigger Replacement in Titronics Thermal Scanners

The trigger assembly in the C-3000, C-4000, C-5000, and C-6000 scanners consists of the following parts:

The Stainless Steel trigger A stabilizing plastic sleeve A spring One or Two 4-40 Allen set screws (depending on scanner model

If, over time, a set screw has loosened and the trigger has fallen out, try to locate the above 4 items. More than likely the sleeve, spring, and Allen set screw(s) are still within the scanner. Use the 7/64" Allen wrench on the plastic screws to remove the handle from the head. Carefully lay the handle and the head down so as not to stretch or separate any of the wires. Locate any of the above parts that may have fallen into the handle.

When replacing the trigger you will need a 0.050" Allen wrench. Not all Allen wrench sets you will find at a hardware store go down to this size. Check the package to make sure:



The order that the parts go back into the handle is as follows:

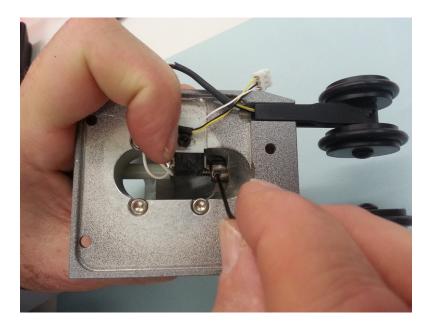


The plastic stabilizing sleeve will "click" into a round cutout in the back of the handle as you insert the pieces. Do this in such a way to keep clearance between the assembly and the wires or cables between the handle and head. The metal tab on the switch should not be caught in any of the spring loops, but should be up against the rear of the main trigger body.

Place an Allen screw on the end of the .050" Allen wrench (long side) and lay it down where you can easily reach it.

Insert the spring on the trigger tail, followed by the plastic sleeve, and carefully slide the assembly back through the trigger "hole" in the handle.

Use one hand to keep the trigger inserted all the way, exposing the female 4-40 threaded holes in the main body of the trigger.

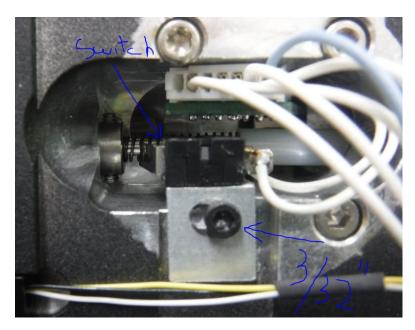


Carefully pick up the .050" Allen wrench with your other hand, holding it up as not to lose the small Allen screw being held on by gravity and tighten it into the threaded hole in the main trigger body. The earlier C-3000 and C-4000 scanners may only have one Allen holding in the trigger.

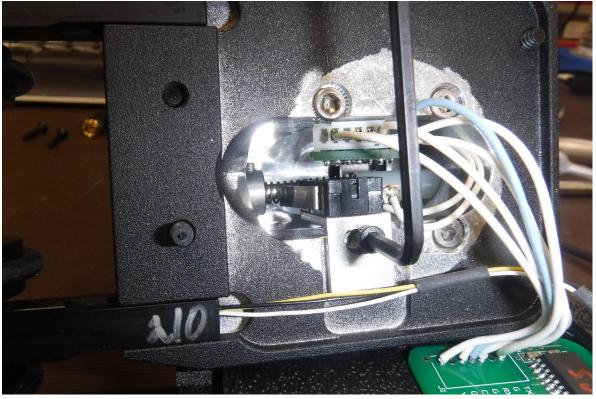
IF YOU ADJUST THE POSITION OF THE SWITCH BRAKET – MAKE SURE IT'S FAR ENOUGH BACK THAT SQUEEZING THE TRIGGER DOESN'T PUSH AGAINST THE BODY OF THE TRIGGER AND SHEAR IT OFF OF THE ALUMINUM BRACKET.

8.4.4 Trigger Assembly Replacement and Adjustment – CRITICAL

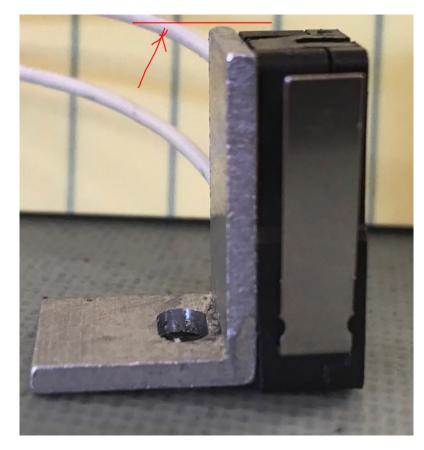
Remove the defective trigger switch assembly using the 3/32" Allen wrench, unplug the leads going to the female socket on the handle board. Plug in the leads from the new switch and mount the new assembly as shown.



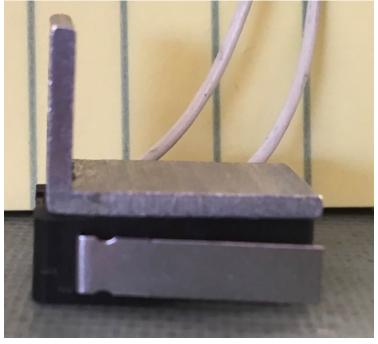
In the new model scanners, the adjustment bolt requires a 3/32" Allen wrench. The position of the switch should allow the trigger to push the activating lever up against the switch body BUT NOT allow any further pressure that might break the switch free of the adjusting plate.



If the micro switch itself just became detached you may re-attach it following the instructions below. The positon that it is epoxied back to is critical:



When you re-attach the switch (clean / sand surfaces first) use 2 part quick set epoxy and make sure the BRACKET and PIASTIC trigger housing are EVEN – if the trigger haqngs too low – the metal "finger" will catch on the spring.



8.4.5 Replacing scanner wheel assemblies

Replacing the Tytron Scanner Wheels

Required tool - 7/64["] Allen Wrench – remove 4 plastic screws holding handle to head Required tool - 0.050" Allen Wrench to "loosen" the 4-40 set screws securing barrels

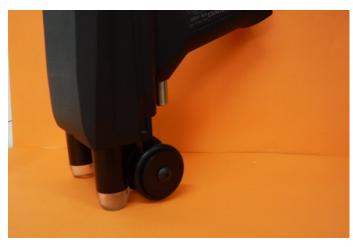
Right Wheel Replacement and "Adjustment

To replace the **RIGHT** (idler) wheel and "arm" use the 0.050" Allen Wrench to loosen the two 4-40 set screws holding the "arm". The "arm" will pull out, insert the new "arm".

NOTE: The small 4-40 Allen set screws may be very tight - use the short end of the Allen wrench and make sure it is inserted into the screw head as far as possible before you try to loosen them - just enough to free the "arm" holding the wheel assembly.



When the new "arm" is in place, check its position by adjusting it carefully before tightening the 2 set screws for "balance" (perpendicular) and "square" (matching the other wheel).



The wheels should be positioned to the scanner doesn't "rock" side to side when the barrels are on a flat surface.

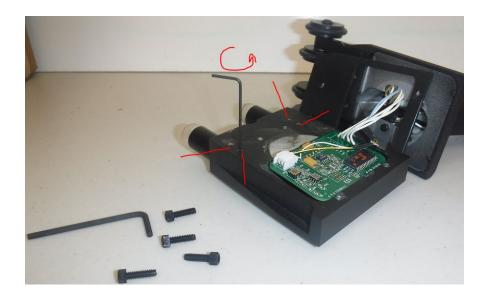
When both barrels and both wheel assemblies are on a flat surface the back of the "head" should be just a little forward of horizontal (level). This will allow the barrels to glide about 1/8 inch off the skin while holding the

scanner in a comfortable position for the operator.

Left Wheel Replacement

To replace the **LEFT** (measuring) wheel, first loosen the two 4-40 set screws that are holding it into the handle. Don't pull it out yet, just loosen it. There is a 3-wire signal cable attaching it to the circuit board in the head. The scanner handle must be carefully removed and set over on its side. Use the 7/64" Allen to remove the four 6-32 pan head bolts as shown:





With the handle off to one side, remove the male white plug from the socket on the computer (A to D board). It is tight – a small screwdriver may be used to "pry" them apart or the "nose" of a small needle nose plyer.



After the wheel sensor cable is separated from the socket, it can be "snaked" through the black gasket and the LEFT measuring wheel can be removed and replaced. The above steps in reverse order will allow the new wheel assembly to be installed.

REMEMBER to "snake" the new cable through the black gasket before plugging it back into the A to D board.

Carefully replace the handle to the head and adjust the LEFT wheel arm as discussed previously for the right "balance" and "square".

9 DISPOSAL

The C-5000 may be disposed of without concern for any toxic substances, 95% of the scanner is Aluminum and stainless steel. These can be re-cycled by opening the scanner and removing the two circuit boards. The circuit boards are RoHS Compliant based on the EU RoHS 2. Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE). There are no batteries in the C-5000.

There are no microbial hazards such as explants, needles or harmful chemicals in the instrument. There are no physical hazards such as from sharps. If in accordance with the point (d) of Section 23.1 of the Regulation no instructions for use are required.

9.1 How to Disassemble the Product

Use the 7/64" Allen wrench (supplied in the spare parts envelope) to remove the four 6-32 screws holding the handle to the head. The two circuit boards may be un-plugged and re-cycled as required in your region. They are RoHS 2 compliant and are safely disposed of a electronic components as outlined in 4.3.5. (Disposal of electronic components.)

9.2 How to Recycle Parts

The aluminum head and handle should be re-cycled as they are valuable materials. They may be disposed of as unsorted waste- but that would be a shame, as aluminum is a valuable metal.

9.3 How to Dispose the C-5000 scanner

There is no test procedure to facilitate safe disposal of the device, when it fails to operate it may be safely repaired or disposed of as an electronic component, if the circuit boards are removed as outlined in 4.1, they may be disposed of as outlined in 4.3.4. (Disposal of electronic components.)

9.3.1 Related waste substances

The USB cord may be disposed of as an electronic component section 4.3.5.

To test the product before disposal:

Double check with the technically qualified IT person with knowledge of the C-5000 to make sure that after following all the trouble shooting guides the scanner is nonfunctional there are two choices: 1) return to the manufacturer for repair (recommended) 2) follow disposal procedures.

9.3.2 Disposal of the device

To dispose the device:

After it is disassembled (section 4.1) follow 4.1 to recycle or 4.3 to dispose.

9.3.3 Disposal of electronic components (circuit boards and USB cord)

The symbol on the product, the accessories or packaging indicates that this device must not be treated as unsorted municipal waste but must be collected separately! **Dispose of the device via a collection point for the recycling of waste electrical and electronic equipment if you live within the EU and in other European countries that operate separate collection systems for waste electrical and electronic equipment**. By disposing of the device in the proper manner, you help to avoid possible hazards for the environment and public health that could otherwise be caused by improper treatment of waste equipment. The recycling of materials contributes to the conservation of natural resources. Therefore, do not dispose of your old electrical and electronic equipment with the unsorted municipal waste.

Disposal of packaging waste



The packaging is made of environmentally friendly materials, which may be disposed through your local recycling facilities. By disposing of the packaging and packaging waste in the proper manner, you help to avoid possible hazards for the environment and public health. The

symbol on the packaging indicates that the packaging is made of PAP.

The metal case may be disposed with unrecycled waste.

9.3.4 Disposal of batteries the C-5000 does not contain a battery.

10 Frequently asked questions

10.1 Will the Tytron software work on my computer?

The Tytron software is written for a Windows operating system. It will run on Windows 7, 8, and 10.

Windows XP is no longer supported by Microsoft and as of April 2017 they do not support Windows Vista. Thus, Titronics will not support the software on those operating systems. System Requirements: Windows 7/8/10 · Pentium II Processor or Greater · 200MB Free Hard Drive Space · CD-Rom Drive or USB Port for installation and at least 1 USB port for scanner connection.

10.2 I have installed the software, but I can't scan.

The registration number needs to be placed in the software in Setup on the Main Tab. The scanner needs to be detected in both the computer and the software.

If you have a C3000/C4000 scanner, also check the power supply. You should see a red light in the black and white wheel hub.

C3000 and C4000 are serial scanners that need to find the correct COM port found in the Device Manager and then put in the software. Make sure that the Serial Scanner 1 is enabled in the Scanner tab of the Setup, there too you will be able to input the correct port number that you found in the Device Manage.

C5000 and C6000 are USB connection and can be found in the Device Manager under USB Connections. No ports are needed to be put in the software. In this case, most standard drivers can be found on Titronics website under Resources or on the flash drive under drivers.

10.3 My lines graphs are fine, but the bar graphs are all to one side and green.

In the Setup on the Scans Tab, there is an option of Center Bar graph. That should be checked YES. This is also an indication that your scanners calibration might need to be checked.

10.4 My lines graphs are fine, but the bar graphs are all to one side and green.

In the Setup on the Scans Tab, there is an option of Center Bar graph. That should be checked YES. This is also an indication that your scanners calibration might need to be checked.

10.5 Restoring a Broken Data Base

Close the software on all computers that are networked.

On the server computer, open the C3000 folder on the C drive. There you will find DB fixer. Click on that and hit the Rebuild + Fix All button. This might take a few minutes.

r C.\C3000\DB\		
Rebuild + Fix All	0%	
Just Rebuild All	DB path set to: C:\C3000\DB\	,
Table Status		
Header:		
Treatment.		
Indexes:		

If your DBfixer does not look like this, please update your software version or call in to get the latest update. This should be done as needed.

10.6 I am getting an 'index out of date' error when I pull up my software. What do I do?

Close the software and do Database Maintenance. Remember, if your software is networked you will have to close the software on all the computers and perform the maintenance on the server.

10.7 Can I use the software on multiple computer in the office?

Yes! Networking the software can be accomplished if all the computers are networked in the office first. The computer to be used as the Server needs to share the C3000 folder with full access and each of the Clients (and the Server if it is using the software also) need to point to the database in Setup. The Data Folder should be set to *ServerName*C3000DB

10.8 What are the scanning modes for the Tytron software?

If a scan is 25cm or less, the software recognizes it as a **Cervical Scan**, anything longer is a Full Spine. There are also the modes of **Scan Segment** and **Infant Scan** located at the top right of the scan screen. Segment scan allows you to read the lumbar, skip the thoracic, and continue with cervical scan.

The **Segmental** mode allows performing a lumbar and a cervical scan, while omitting the thoracic region (to avoid clothing). Simply lift the back covering to expose the lumbar and lower the back covering to expose the cervical. To do this, click Scan on the home screen to display a blank scan screen. Click the Segment button, located at the top right corner of the screen. To record all data properly, place the scanner probes $\frac{3}{4}$ " lower than the desired starting point. To start, pull the trigger and scan the lumbar region, then release the trigger. Next, place the scanner just below T1, pull the trigger again and complete the cervical scan, then release the trigger. The full spine line or bargraph displays with no lines/bars in the mid spine area.

Scanning infants adheres to the same rules as adults. However, the fixed probe width being wider than an infant's neck necessitates a special protocol. Use only the left barrel to scan both sides of the spine, one side at a time. Once a patient has been selected via the Load Patient File function, follow these steps:

1. Bring up the scanning screen by hitting the S key or clicking the Scan button on the home screen. A blank screen displays.

2. Before starting to scan, mark a starting reference point for the scans. Using a washable marker, draw a horizontal line across the spine as a starting point (remember to carefully palpate for cervical or full spine starting point before drawing the line).
 3. Select the Infant Mode by hitting the I key or clicking on the Infant button at the upper right corner of the screen. On the scanning screen instructions will be displayed.
 4. Always start with the right paraspinal surface first. Place the wheels of the left barrel on the right paraspinal surface while maintaining the probe tip just above the skin and exactly on the drawn horizontal starting line.

5. Pull the trigger, but do not begin scanning immediately! First, a tone sounds (if sound is enabled) and the software displays a screen prompt reading Initializing Sensors. Next, a second tone sounds and the software displays a screen prompt reading Scanning, signaling to begin the scan.

6. Scan upward towards the head with an even cadence while maintaining the left probe tip just off the skin. When the hairline is encountered, gently press the probe down onto the skin to displace the hair. Stop the scan when the occiput is encountered and release the trigger before lifting the scanner off the spine. A screen prompt displays, reading Ready to Scan.

7. Now, place the wheels of the left barrel on the left paraspinal surface while maintaining the probe tip just above the skin and exactly on the drawn horizontal

starting line.

8. Again, pull the trigger and wait for the set of tones or prompts indicating to begin the scan. However, this time do not stop at the occiput! Scan just past the termination point of the right paraspinal scan and release the trigger (the computer references the distance of the scan to the starting line and only saves the exact same amount of infrared signals as the right paraspinal scan).

Once the left side scan is complete, a thermal plotted graph immediately displays on the screen. Hit the Esc key to save the scan. Unlike scanning adults, infant scan repeatability is dependent upon the scanner's wheel encoder and the starting point of the scan. The reference point of each scan is the drawn horizontal starting line. Consequently, the only error involved is the ability to start the scan at the same point each time.

10.9 Data Base error - how do I rebuild the files in the Patient DB files in the C-3000 folder?

Open Drive C, open the C3000 folder, double click on DBFixer.exe

10.10 How do INSTALL / BACKUP / RESTORE the Tytron Software & Patient DATA from a USB Flash Drive?

View the contents of the Flash Drive and double click on the Titronics.exe file.

10.11 SCANNER SOFTWARE INSTALLATION / BACKUP / AND RESTORE PROCEDURES

Insert the Flash Drive into the USB Port – a window should open, Choose **Open Folder to View Files**

Double Click on Titronics.exe

Choose Install Scanner Software

Choose **YES** to allow full setup.

On the Welcome to the TyTron 2.2 Setup Wizard screen click on "Next".

After reading License Agreement, choose "I Agree"

On the **Choose Components screen**, put a **ck** in the **Technical Support Box** if you want an ICON on your desk top that will automatically connect you through LogMeIn.com to our help desk for online support, then click on **"Install"**

Allow the Borland Database Engine Installation – click on the **OK** box.

IF A MESSAGE COMES UP THAT SAYS "THERE IS NOT ENOUGH SPACE", CLICK THE **YES** BOX – NEARLY ALL COMPUTERS HAVE SUFFICIENT SPACE – sometimes they display this message. On the next screen, click on the Next box to allow Instant Support to install in the prompted location.

Chose Next again on the Ready to Install screen.

Allow a few seconds for Titronics Instant Support to be installed. This will place an ICON on your Windows[™] desk top. Should you need Titronics tech support – this will send to our service center your location and alert us to connect.

Continue to choose suggested options and click Finish – that will leave the following window up that will allow you to connect to our tech support person.

If you do not want to connect at this time just close this box.

10.12 TYTRON DATA BASE BACKUP PROCEDURES

Insert a Flash Drive in the a USB Port.

You may **X** out of this window.

Start the TyTron program and from the **HOME** screen of the TyTron Paraspinal Infrared Imaging software, click on the **Backup** button in the upper right section of the screen. A popupbox will appear and ask if you want to shut down this program. Choose **Yes** The program will close (close the Tytron software on any other networked computers as well).

Click on the Browse button.

Highlight the Removable Disk Location.

Click **OK** this shows the **Drive** that has been selected to copy your data to. Click **GO** Click **OK**, and you are finished the backup procedure.

Keep your Flash drive in a secure location, perhaps do one every week / month, what ever you feel comfortable with and rotate several at a different location.TyTron Software Database Restoration

If the computer malfunctions, causing damage to the patient database, the Database Restoration process will restore the database back to the point of the last backup. The Database Restoration process only works if the patient database has been previously backed up!

To perform a restoration,

- 1. Close the Tytron Program on all computers on the network
- 2. Insert the flash drive that contains the database backup files
- 3. Open the drive containing the backup
- 4. Click on open folder to view files.
- 5. Double click the backup zip (TytronBackupMM-DD-YYYY.zip),
- 6. Copy all the files
- 7. Locate Drive C and open the C3000 folder and then the DB folder:

- 8. Right click once and select/right click PASTE (If the data base is empty this should copy in the files you copied in step 4 from the old computer's data base).
- 9. **BEFORE** you **Select Copy and Replace**, check the box at the lower left corner "Do this for the next xx conflicts"
- 10. Database Restoration is complete.
- 11. Run the Tytron Program to verify successful restoration by loading a patient

10.13 I just bought a scanner from another doctor; do I need to contact Titronics?

Titronics is under FDA guidelines. This means that Titronics is responsible for keeping a record of where the devices are. A transfer of a scanner from Doctor to Doctor can be done over the phone. There is a transfer fee involved. Call into the office for more information. 319-545-7377 or email <u>cathy@titronics.com</u>

10.14 What keyboard functions do I use in the software to get <u>???</u>, view the chart in section 2.11

10.15 How can I email a scan to a patient?

Emailing options are available in the software under the Printing tab of the Setup The Use MAIP option will use your Email client (Thunderbird, etc.) to send mail. The E-Mail Settings(SMTP) area allows you to configure the software to send mail directly through your E-Mail server. Consult with you E-Mail provider for information on these settings.

If all else fails, print a scan to PDF and then attach it to an email using your email server.

10.16 What are the functions of all the buttons to the left of the patient home screen?

F1 Pre: Displays the last pre-adjustment scan performed.

F2 Pat + Post: This function serves two purposes. First, a patient's pattern is displayed with the last post-adjustment scan overlaid, allowing the patient to see results of their last adjustment. Second, use the C key to look back through post-adjustment scans in detail to determine the effectiveness of adjustments. (See Scan Utilities below for how to set a pattern)

F3 Pat + Pre: This function also serves two purposes. First, a patient's pattern is displayed with the last pre-adjustment scan overlaid, to objectively present data supporting your decision along with other findings to adjust or not adjust at visit. Second, use the C key to look back through preadjustment scans in detail.

F4 Scan Utilities:The Scan Utilities screen has 9 basic functions. Click the Scan Utilities button or hit the F4 key while at the Home Screen to perform scan utilities. First, a scan must be selected to perform a scan utility function (either click on it or select the corresponding letter) — the exception to this in the Any 2 Scans function. 1 View: Views the selected scan. This can also be performed by double clicking the scan

or hitting the Enter key.

2 Any 2 Scans: Displays an overlay of 2 selected scans. Select the scans after hitting this button by clicking on the desired scans or pressing the corresponding letters.

3 View /w Pat: Displays the selected scan overlaid with the patient's selected pattern. 4 Pre/Post: Changes the selected scan from a pre-adjustment scan to a post and vice versa.

5 Edit Scan: Edits the Note, Listing, Comment, Pre/Post designation, Pattern fields and options for a scan. The Note field allows notes up to 4 characters long (i.e. MVA). Editing the Listing changes the listing for the currently selected scan only. The Comment field allows up to 255 characters of information (i.e. SOAP notes).

6 Make Pat: Marks the selected scan as the patient's pattern.

7 Delete Scan: Permanently deletes the scan from the selected patient's database. Delete Patient: Permanently erases the patient and all their scans. This cannot be undone! Export to CSV: Exports the scan list to a .CSV (comma separated values) file. **F5-F8:** The History Manager allows for quickly monitoring the details and results of care. Hitting the Page Up and Page Down keys while viewing a patient that has more scans than displayed on the screen allows for the viewing the additional scans from the patient's history. The History Manager functions are discussed in more detail in the History Screen section on page 28.

F5 Pat + 9: Displays the patient's chosen pattern in the upper left hand corner along with the last 9 scans in the database. This allows the ability to review the progress of care and evaluate both the chosen pre-adjustment scan and the effects of the adjustment on the post scan.

F6 Pat + Pre: Displays the patient's chosen pattern in the upper left hand corner along with the last 9 pre-adjustment scans in the database to quickly evaluate if a new pattern is forming.

F7 Pat + Post: Displays the patient's chosen pattern in the upper left hand corner along with the last 9 post-adjustment scans in the database to quickly evaluate if rendered adjustments are effective.

F8 Pat + Pre when Post: Displays the patient's chosen pattern in the upper left hand corner along with the last 9 pre-adjustment scans when a post adjustment scan is performed. This allows the ability to evaluate if the pre-adjustment scans match the pattern or if over-adjustments are performed.

F9 Pre/Post: Quickly toggles the last scan taken between a Pre and a Post Adjustment. **F10 Comment:** Displays the comment field for the last scan taken. The comment field allows up to 255 characters of information, for comments such as SOAP notes.

F11 Change Listing: Changes the listing for the last scan taken. This differs from the editing function in the Scans Utilities area. This function updates the displayed home

screen listing and all subsequent scans performed.

F12 Select Scans: Allows the selection of up to 10 scans for individual history viewing. Once the scans have been selected, click OK or hit the Enter key to view the scans. Hit the Esc key to return to the Select Scans screen. Click the Clear button to clear previously selected scans or Esc again to return to the home screen.

NCM: Loads the NCM Screen. See page 29 for more details.

Scan: Hitting the S key allows for a simple scan to be taken without a pre-adjustment or pattern overlay. Multiple scans may be performed in this manner, however only the last scan taken will be saved in the patient's file upon exit. To save multiple scans press the Enter key after taking each scan.

10.17 Do I need to back up my database?

Yes, it is highly recommended to backup you database. There is an option in Setup, that you may choose to turn on that will remind you whenever you exit the program.

11 APPENDIX I – SUPPLIED ACCESSORIES, CONSUMABLES AND SPARE PARTS

Image	Name	Article Number
	USB A-B cord – 10 foot - connects C- 5000 to host computer	Insignia [™] - 10' USB 2.0 A-Male-to-B- Male Cable - Black Model:NS-PU105AB SKU:5883001
(4 count)	Large (inner) rolling wheel tire	McMaster-Carr Chicago, Illinois USA # 9452K31- 213
(4 count)	Small (outer) rolling wheel tire	McMaster-Carr Chicago, Illinois USA # 9452K31- 213
	3/32" Allen Wrench	McMaster-Carr # 7122A42
\sim	0.050 " Allen Wrench	McMaster-Carr # 7122A13
	7/64" Allen Wrench	McMaster-Carr # 7122A42
(8 extra in kit)	6-32 x ¹ /2" Allen nylon screws	Titronics R & D Tiffin, Iowa USA

11.1 Supplied accessories -

4-40 x 3/16 Allen head set screw	McMaster-Carr # 92765A005

11.2 Consumables - may be ordered from Titronics Website

Image	Name	Article Number
0	Large (inner) rolling wheel tire	McMaster-Carr Chicago, Illinois USA # 9452K31- 213
0	Small (outer) rolling wheel tire	McMaster-Carr Chicago, Illinois USA # 9452K31- 213
	USB A-B cord – 10 foot - connects C- 5000 to host computer	Insignia [™] - 10' USB 2.0 A-Male-to-B- Male Cable - Black Model:NS-PU105AB SKU:5883001

11.3 Replacement parts - order from Factory (cathy@titronics.com)

Image	Name	Article Number
	Trigger Switch Assembly	Titronics R & D Tiffin, Iowa USA

	Trigger micro switch	Titronics R & D Tiffin, Iowa USA
(4 per package)	6-32 x ¹ / ₂ " Allen Head plastic screws	Titronics R & D Tiffin, Iowa USA – Website -

EU Declaration of Conformity				
1. Product model: Tytron C-3000, 4000, 5000, 6000, and 7000				
 Name and address of the manufacturer or his authorized representative: Company: Titronics R&D Company Postal address: P.O. Box 470 Street Address: 400 Stephans St. Ste. D City and State: Tiffin, Iowa 52340 Telephone Number: 319-545-7377 E-mail address: info@titronics.com 				
This declaration of conformity is issued under the sole responsibility of the manufacturer.				
4. Objective of the declaration: Equipment: Temperature Measuring Probe/Scanner Brand name: Tytron Model/type: C-3000, 4000, 5000, 6000, and 7000 Descriptive information: Class I Non-diagnosing, measuring Medical Device				
 The object of the declaration described above is in conformity with the relevant Union harmonization legislation: Regulation on Medical Devices EU 2017/745 Measuring Instruments Directive 2017/32/EU Product Liability directive 85/374/EEC Instructions for Use Manual Guidelines MDD 93/42 EEC Annex 1, Section 13:6 Guidelines on Medical Devices Vigilance System MEDDEV 2.12-1 Rev. 8 Guidelines on Medical Devices Clinical Evaluation MEDDEV 2.7/1 Rev. 4 Application of Risk Management to Medical Devices ISO 14971:2016 Medical Device Quality Management System ISO 13485:2016 				
6. The manufacturer has appointed MDSS as its Authorized Representative: EC REP MDSS GmbH Schiffgraben 41 30175 Hannover, Germany				
7. Signed for and on behalf of: Manufacturer/Authorized representative: Roger Titone Company: Titronics R&D Company Place: Tiffin, IA USA Date:				
 Titronics				

12 CLINICAL EVALUATION

[Make sure that the clinical evaluation as most recently updated, is appropriately reflected in the instructions for use and, where applicable, the summary of safety and performance]

The use of thermography is well past the investigational or experimental stage and is approved for clinical use by the FDA. On review of the relevant research at the time, the Department of Health Education and Welfare (HEW) declared thermography non-investigational in 1972. Thomas Tierney, then director of the department of HEW, stated that "the medical consultants indicate that thermography in its present state of development is beyond the experimental state as a diagnostic procedure in the following four areas: 1.) Pathology of the female breast, 2.) Extra-cranial vessel disease, 3.) Peripheral vascular disease, and 4.) musculoskeletal injury." In 1982, the FDA approved the use of thermography and stated that "....thermography can be a useful adjunct for diagnosis in many areas, including musculoskeletal injuries." This classification was published in the Federal Register: Vol 147, No. 20, pp 4419-4420, January 29, 1982.

1972 First Position Paper of the U.S. Department of Health, Education and Welfare on Thermal Imaging Thomas Tierney, Director of US Dept. of HEW "the medical consultants indicated that thermography in its present state of development is beyond the experimental state as a diagnostic procedure in the following four areas...1. Pathology of the Female Breast 2. Extra-cranial Vessel Disease 3. Peripheral Vascular Disease 4. Musculoskeletal Injury"

1982 FDA - Bureau of Medical Devices, Health and Human Services on Thermography Acting Bureau Director ... "thermography can be a useful adjunct for diagnosis in many areas, including musculoskeletal injuries"

1982 Federal Drug Administration proposed classifications for thermographic systems.

Published classifications in Federal Register, Vol 147, No. 20 pp 4419-4420, January 29, 1982

Thermographic paraspinal graphing has been performed clinically since 1920 the preponderance of literature both in the area of chiropractic and medical treatment supports its use in the assessment of neuropathophysiology. (See the References section under 2.9 for a very partial view of current literature).

The manufacturer of the Tytron series of thermal paraspinal instruments has worked with over 4000 chiropractors that rely on accurate thermal graphing of their patient's backs as part of their examinations. The precise repeatability of the Tytron series of instruments is critical to their best practice requirements. In over 30 years there has not been one incident of any one being harmed in any way. In most cases, the advantage provided to the doctor by the additional ability to view objective thermal "post scans" significantly augments the decision making process in establishing the best listing for the chiropractic adjustment.

For further documentation and information on clinical evaluation see Clinical Evaluation Report in accordance with MEDDEV 2.7/1 revision 4

13 RELATED DOCUMENTATION

#	Document Title	#	Location	Author

14 SAFETY SIGNS

14.1 ISO 3864 Safety Signals



14.2 ANSI Z535.6 Safety Signals







