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Indications For Use:

The iTrac is intended for use as a conservative treatment alternative in patients presenting with cervicogenic pain symptoms of mechanical origin related to reduced cervical lordosis/extension and altered posture. It temporarily positions the cervical spine into an extension posture of varying degrees, as determined by a clinician. This device is for prescription use only and is not provided in a sterile condition.

Contraindications:

- Patients with pathological lesions or congenital deformities of the vertebral column that disrupt the integrity and stability of the vertebral and ligament structures.
- Neoplasm, spinal tumors; both metastasis and primary.
- Spina bifida or pars defect.
- Rheumatoid arthritis
- Spinal cord compression
- Malignancy
- Patients with notable posterior spurring of their cervical vertebra
- Patients with spondylolisthesis Grade 2 or greater
- Patients with connective tissue disease; i.e. Scleroderma
- Post-surgical patients who have had spinal surgery and healing of tissue is still required. (The period of time post spinal surgery will vary between 6 months to a year)
- Pregnancy
- Patients with any other conditions that may be made worse by distraction of the spine
- Patients with structural disease due to tumors or infection (e.g., osteomyelitis, spinal caries, and ankylosing spondylitis).
- Patients with joint instability, hypermobility or spinal fracture.
- Patients with osteoporosis.
- Patients with severe cardiovascular disease, vascular compromise, aortic aneurysm or severe respiratory disease.
- Patients where movement is contraindicated.
- Patients with acute sprains, strains or inflammation that could be aggravated by traction.
- Stop traction if there is an increase in radiated pain to the extremities (radicular pain).
- Patients with large posterior disc bulges or herniations.
- Patients with cervical spinal stenosis.
- Patients with cervical vascular compromise.
- Patients with acute sprain, strain and/or inflammation of the cervical joints.
- Patients with internal spinal fixation hardware.

Relative Contraindications (require special monitoring or should be avoided):

- Hiatal hernia
- Claustrophobia

Caution: Federal law restricts this device to sale by or on the order of a Physician.

Treatment should only be administered under the presence of a doctor or therapist. The doctor or therapist should be present at all times and supervise the treatment.

Precautionary Definitions

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows;



= **CAUTION-** Text with a "CAUTION" indicator will explain possible Safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.



= **WARNING-** Text with a "WARNING" indicator will explain possible Safety infractions that will potentially cause serious injury and equipment damage.



= **DANGER-** Text with a "DANGER" indicator will explain possible Safety infractions that are imminently hazardous situations that would result in death or serious injury.

Device Symbol Definitions



Pinch Point Keep hands clear of moving parts.



EXPLOSION HAZARD - possible explosion hazard if used in the presence of flammable anesthetic.



See Manual for warnings and instructions



Type B

Electrical Type Rating – Type B



Recycle and dispose of device properly in accordance with local, state and federal laws. Over the years, tons of electronics equipment with hazardous materials have been thrown away with standard garbage. Over time, these materials leech out of the electronic causing damage to the environment. It is important to try and properly dispose of retired devices in order to prevent damage to our environment.



CAUTION

Precautions

- Read, understand and practice the precautionary and operating instructions found in this manual. Know the limitations and hazards associated with your new treatment device. Observe any and all precautionary and operational decals placed on the device.
- Grounding- Make certain that the device is connected to a power source appropriate for your equipment. Ensure your equipment is grounded by using a 3-prong electrical outlet. A ground wire must be connected to the ground stud in the control tower if a 3-prong electrical outlet is not available.
- Keep device out of high moisture areas.
- This unit should be operated, transported and stored in temperatures between 40° F (4.4° C) and 100° F (37.8° C), with relative humidity ranging from 30% - 80%.
- DO NOT operate this device in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this device on and off. Try to correct the interference using one or more of the following: reorient or relocate the receiving device, increase the separation between the equipment, connect the equipment to an outlet on a different circuit from that which the other device(s) are connected, and consult the Pivotal Health Solutions Service Department for help.
- Inspect all cables and connectors before each use.
- Power rating: T9000: 115 V 60Hz 10 Amp Max. Fuse = T10A

T9010: 230 V 50Hz 10 Amp Max. Fuse = T10A

- Never place your hands or feet near the working mechanism of the device while operating the device.
- Always assist the patient on and off the device to avoid falls.

- Always use the magnet- release coupler to connect traction line to headgear. Never tamper with, or remove, the magnet-release coupler. Never attempted to attach the traction line directly to the headgear.
- Always monitor patients closely during treatment. Do not leave unattended.
- Treatment should only be administered under the presence of a doctor or therapist. The doctor or therapist should be present at all times and supervise the treatment.
- The device's maximum safe working load is 350 pounds. Never exceed the maximum load limit.
- Do not permit any foreign materials or liquids to enter the unit. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from entering the unit. These may cause unit damage, malfunction, electrical shock fire or personal injury.
- The Patient Stop Switch is essential for the functioning of the unit. If it is not connected, or if it is malfunctioning, do not operate the unit.
- Do not use a damaged Mains Power Cord. Using a damaged Mains Power Cord may cause unit damage, malfunction, electrical shock, fire, or personal injury. If the Mains Power Cord becomes damaged, discontinue use immediately and contact the dealer for replacement of the Mains Power Cord.
- DO NOT adjust column height while patient is attached with harness.
- IF THE PATIENT EXPERIENCES ALTERATIONS OF SPEECH, SIGHT, TASTE, HEARING, SMELL OR FACIAL PAIN, NUMBNESS OR WEAKNESS WHILE OR AFTER THE TRACTION SESSION, IT IS RECOMMENDED THAT YOU IMMEDIATELY DISCONTINUE THEIR USE OF THIS DEVICE.
- IF THE PATIENT RE-OCCURING EXPERIENCES DIZZINESS OR A LIGHT-HEADED SENSATION WHILE OR AFTER THE TRACTION SESSION, IT IS RECOMMENDED THAT YOU REDUCE THE TRACTION POUNDAGE. IF THIS DOES NOT ALIVIAE THE SYMPTOMS, IT IS RECOMMENDED THAT TYOU IMMEDIATELY DISCONTINUE THEIR USE OF THIS DEVICE.



DANGER

- Possible explosion hazard if used in the presence of flammable anesthetics.




TABLE OF CONTENTS

REMOVING FROM SHIPPING MATERIALS.....	8
SECTION I – EXPLANATION OF FEATURES.....	8
SECTION II – TRACTION THERAPY PROCEDURE.....	12
SECTION III· TREATMENT EXAMPLE	42
SECTION IV – SOFTWARE: INSTALLATION, SETUP & OPERATION	43
SOFTWARE INSTALLATION.....	44
SOFTWARE USER SETUP	51
SOFTWARE USER OPTIONS.....	52
SOFTWARE OPERATION.....	52
CARE & MAINTENANCE	77
TROUBLESHOOTING	82
REPLACEMENT PARTS & ACCESSORIES.....	84
WARRANTY AND REPAIR.....	84

Removing from Shipping Materials

1. Do not tip unit on its side, as oil may leak from the air compressor.
2. Remove packaging materials.
3. Allow unit a minimum of 6 hours to reach room ambient temperature (above 60° F) before use.

Section I – Installation and Explanation of Features

- 1)  **WARNING** When moving the iTrac do not push or pull on cushions or fulcrum section. Do not lay iTrac on its side or stand the device on end. If the device needs to be moved use the transport handle and casters.
- 2) Place the iTrac device on a flat level surface.



- 3) Plug the power cord into proper wall outlet (see serial decal for rating).
WARNING: to avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- 4) Check iTrac device functionality:
 - a) Press the Column Up Button. The Column will elevate until end of stroke is reached.
 - b) Press the Column Down Button. The column will lower until end of stroke is reached.
 - c) While supporting the fulcrum arm press or pull the fulcrum release knob. Move the fulcrum arm up and down to ensure free movement.
 - d) While supporting the traction arm push or pull the traction release knob. Move the traction arm up and down to ensure free movement.

If any of these tests fail or any questions arise please contact customer service.

- 1) **Power ON** – Plug the hospital grade power cord into an appropriate 3-prong electrical outlet conforming to the applicable national and local electrical codes.
- 2) **Patient Stop Switch** - The Patient Stop Switch is an essential safety feature. The control consists of a button on the end of a cord connected to the control console. When the button is pressed, the traction force is gently released without going through ramp down. The patient should hold the Patient Stop Switch during treatment. Patients should be instructed to press the button at any time they want to discontinue treatment.
- 3) **Power Control Box** - The Power Control Box is located at the base of the device. The Power Indicator and power receptacle are located on the Power Control Box.
- 4) **Fold-up Armrests** - The armrests are capable of folding up and back to improve patient comfort in the seated position. To fold the armrests up, raise the front of each armrest up and back until it is at its fullest up position. To unfold the armrests, push forward and down until each armrest is at its fullest down position.
- 5) **Mechanical Adjustments**
 - a) Vertical Height Adjustment – The height of the main Traction/Fulcrum assembly can be varied from a minimum value of 24” to a maximum of 40” using the buttons marked Column UP & Column DOWN respectively.

- b) Fulcrum Angle Adjustment - The Fulcrum can be adjusted to any of (5) adjustments, -20 degrees, -10 degrees, 0 degrees, +10 degrees and +20 degrees.
- c) Traction Angle Adjustment – The Traction can be adjusted to any of (10) settings ranging from “A” to “J”. The letters designate the general angle of pull as measured from vertical;
 - i) Setting “A” equates to -136° from vertical
 - ii) Setting “B” equates to -118° from vertical
 - iii) Setting “C” equates to -100° from vertical
 - iv) Setting “D” equates to -82° from vertical
 - v) Setting “E” equates to -64° from vertical
 - vi) Setting “F” equates to -46° from vertical
 - vii) Setting “G” equates to -28° from vertical
 - viii) Setting “H” equates to -10° from vertical
 - ix) Setting “I” equates to +8° from vertical
 - x) Setting “J” equates to +26° from vertical
- 6) **Capture-** The supplied capture must be used for cervical traction treatments. The headgear is marked "Front" and "Back" and features a surface that can be used against the patient's skin. See Section II, D for detailed information about proper application of the Headgear.
- 7) **Magnet-release Coupler:** The magnet-release coupler is an important safety feature used to attach the patient headgear to the traction line. Always ensure during setup that the magnets are properly aligned (not offset) and making good contact to maintain proper strength. The magnets are designed to decouple the headgear from the traction line, thereby freeing the patient, in the event unsafe forces are reached. **Never remove the magnets or attempt to attach the traction line directly to the headgear.**
- 8) **Re-location/Transport Wheels & Handle** – The iTrac machine can be moved from location to location in the office environment via the integral Transport Wheels & Handle.

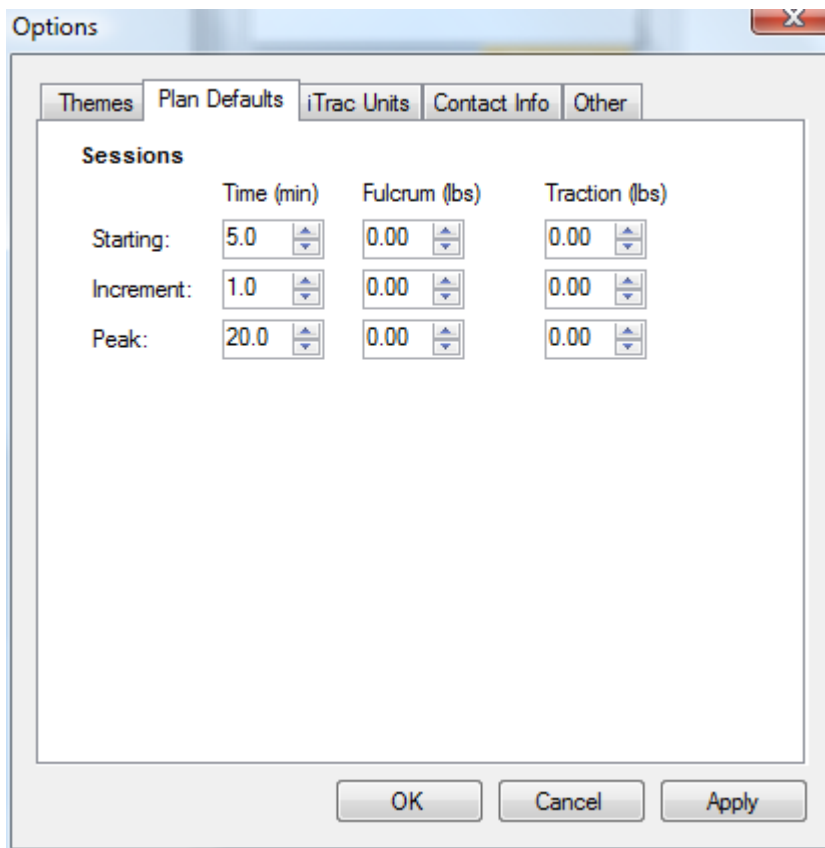


Section II – Traction Therapy Procedure

Establishing Plan Defaults

Available ONLY to a User having DOCTOR or ADMINISTRATOR credentials, this tool may be used to modify the default settings for the following parameters with which New Treatment Plans will be created.

- Treatment Plan **Time**: Starting, Increment and Peak
- Treatment Plan **Fulcrum Force**: Starting, Increment and Peak
- Treatment Plan **Traction Force**: Starting, Increment and Peak



The image shows a screenshot of the 'Options' dialog box in a software application. The 'Plan Defaults' tab is selected. Under the 'Sessions' section, there is a table with three columns: 'Time (min)', 'Fulcrum (lbs)', and 'Traction (lbs)'. The rows are labeled 'Starting:', 'Increment:', and 'Peak:'. Each cell in the table contains a numeric value and a small up/down arrow icon for adjustment. The values are: Starting Time 5.0, Starting Fulcrum 0.00, Starting Traction 0.00; Increment Time 1.0, Increment Fulcrum 0.00, Increment Traction 0.00; Peak Time 20.0, Peak Fulcrum 0.00, Peak Traction 0.00. At the bottom of the dialog box are three buttons: 'OK', 'Cancel', and 'Apply'.

	Time (min)	Fulcrum (lbs)	Traction (lbs)
Starting:	5.0	0.00	0.00
Increment:	1.0	0.00	0.00
Peak:	20.0	0.00	0.00

After a User having DOCTOR or ADMINISTRATOR credentials has modified any Plan Default parameters, clicking the APPLY button saves the changes.



Create a Patient-Specific Treatment Plan (DOCTOR-level credentials are required for access to these parameters)

Click Menu> Patient> New> Plan – The system displays the New Plan screen which contains:

Plan Date – The system displays system date in MM/DD/YYYY format.

Plan Notes Header – The system displays the current patient name and system date

Mechanical Settings: Height – The system displays the default height value

The default setting of “30” is hardcoded and will populate the field. The DOCTOR will direct the input to be altered to the doctor-prescribed height value.

Mechanical Settings: Fulcrum – The system displays the default fulcrum value

The default setting of “0” is hardcoded and will populate the field. The DOCTOR will direct the input to be altered to the doctor-prescribed Fulcrum angle value.

Mechanical Settings: Traction – The system displays the default traction value

The default setting of “A” is hardcoded and will populate the field. The DOCTOR will direct the input to be altered to the doctor-prescribed Traction angle value.



Click Plan Complete – The system designates the current plan as complete as of the system date

Session Information pane – The system displays Session Number, Unit Number, Session Total Time, Session Peak Fulcrum and Session Peak Traction for the 12 sessions comprising this Treatment Plan

Click Save – The system saves changes

Click Cancel – The system closes the New Plan screen

Edit a Patient-Specific Treatment Plan (DOCTOR-level credentials are required for access to these parameters)

Click Edit – The system displays the Edit Treatment Plan screen which contains:

Description-Notes pane – The User may edit the description and add or edit notes related to this Plan

Click Plan Complete – The User may force system to mark this plan as complete

Click Individual Session Information Row – The system displays the Treatment Plan in Edit mode which allows the User having DOCTOR-level credentials to modify the following parameters for the current treatment and all future treatments in the plan

Height – The User selects a height value from the system-provided list

Fulcrum – The User (having DOCTOR-level credentials) selects a fulcrum (angle) value from the system-provided list

Traction – The User (having DOCTOR-level credentials) selects a traction (angle) value from the system-provided list

Time: Current – The User (having DOCTOR-level credentials) may modify the total session time for the selected session

Time: Increment – The User (having DOCTOR-level credentials) may modify the total session time incremental increase for each successive session in the plan

Time: Peak – The User (having DOCTOR-level credentials) may modify the peak session time for all successive sessions in the plan



Fulcrum: Current – The User (having DOCTOR-level credentials) may modify the fulcrum peak force for the selected session

Fulcrum: Increment – The User (having DOCTOR-level credentials) may modify the fulcrum force incremental increase for each successive session in the plan

Fulcrum: Peak – The User (having DOCTOR-level credentials) may modify the peak fulcrum force for all successive sessions in the plan.

Traction: Current – The User (having DOCTOR-level credentials) may modify the traction peak force for the selected session

Traction: Increment – The User (having DOCTOR-level credentials) may modify the traction force incremental increase for each successive session in the plan

Traction: Peak – The User (having DOCTOR-level credentials) may modify the peak traction force for all successive sessions in the plan.

Click Save – The system saves changes

Click Cancel – The system closes the Edit Plan screen

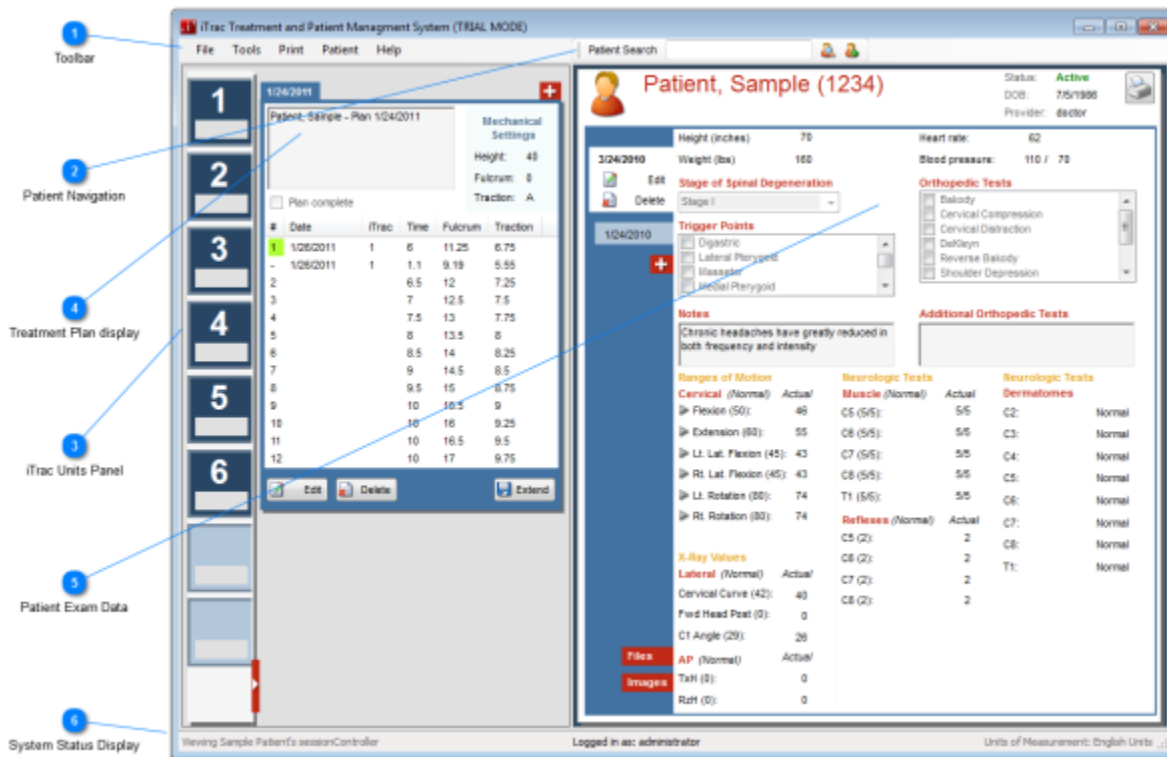
Click Extend – Click Extend - After the final treatment session of a plan is successfully completed, the EXTEND button will appear allowing User to extend the current treatment session plan

*Extend Unavailable in TRIAL Mode - If User attempts to extend a plan while software is operating in Trial Mode, system displays an error screen: "**Cannot extend this treatment plan. If in trial mode, please purchase a valid license and enter key into the Registration form in the Tools menu.**"*

No Active Plan - If User attempts to add a Patient who does not have an active plan to a Unit, the System displays an error screen: No Active Plan "There is not an active plan for (system inserts Patient name). Please create a new plan."

NOTE: Screenshots and more detailed guidance are available in the software Help tool as well as in print form as an appendix to this User Guide.

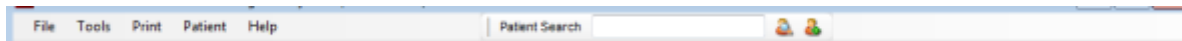
Preparing to Begin Therapy



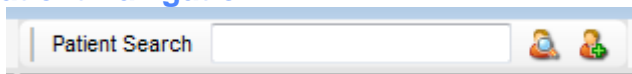
The screenshot shows the iTrac Treatment and Patient Management System (TRIAL MODE) interface. The interface is divided into several sections:

- 1. Toolbar:** Located at the top left, containing icons for File, Tools, Print, Patient, and Help.
- 2. Patient Navigation:** A vertical sidebar on the left with numbered buttons (1-6) for navigating between different views.
- 3. iTrac Units Panel:** A panel on the left showing a list of treatment units with columns for Date, iTrac, Time, Fulcrum, and Traction.
- 4. Treatment Plan display:** A central area showing the treatment plan for Patient Sample (1234), including mechanical settings and a table of treatment data.
- 5. Patient Exam Data:** A panel on the right showing patient information, including Height (70 inches), Weight (160 lbs), Heart rate (62), and Blood pressure (110 / 70).
- 6. System Status Display:** A panel on the right showing various test results, including Orthopedic Tests, Neurologic Tests, and X-Ray Values.

1 Toolbar



2 Patient Navigation



3 iTrac Units Panel



- Displays the installed iTrac Units as numbered and vivid.
- Displays positions available for installation of additional iTrac units as ghosted.

Selecting an iTrac Unit for a Treatment Session

To load a Patient's next available session on to a specific iTrac Unit, Left-Click & Hold on the Patient Name, then drag the Patient Name to and release on the

desired iTrac Machine icon. This can be accomplished from the Patient Exam view (Fig. 1), or from the Patient Search list view (Fig. 2). The Unit Icon border will flash yellow indicating that the selected session for the selected patient is now loaded and in Pause mode on that iTrac Unit.

Fig. 1 - Drag Patient Name to selected Unit Icon from Patient Exam view

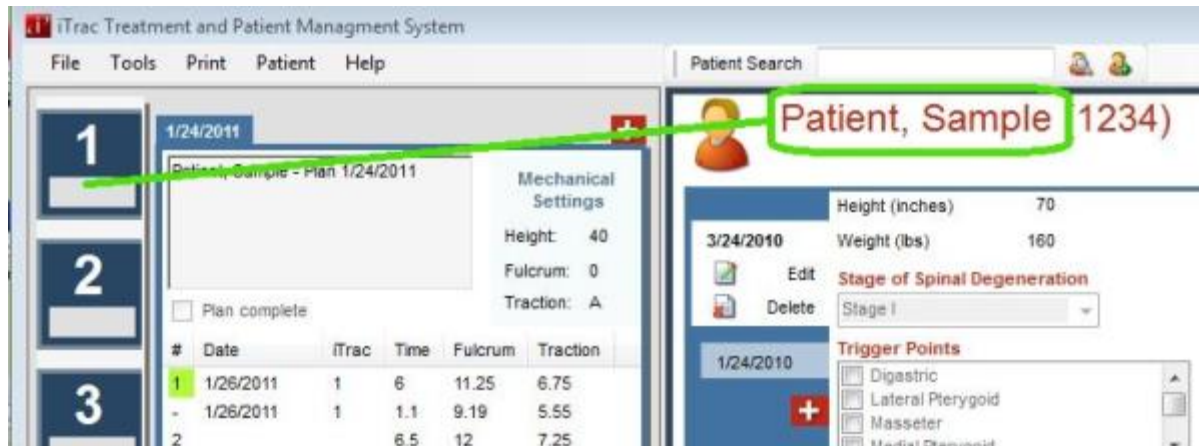


Fig. 2 - Drag Patient Name to selected Unit Icon from Patient Search list view



4 Treatment Plan display

1/24/2011

+

Patient, Sample - Plan 1/24/2011

Plan complete

Mechanical Settings

Height: 40

Fulcrum: 0

Traction: A

#	Date	iTrac	Time	Fulcrum	Traction
1	1/26/2011	1	6	11.25	6.75
-	1/26/2011	1	1.1	9.19	5.55
2			6.5	12	7.25
3			7	12.5	7.5
4			7.5	13	7.75
5			8	13.5	8
6			8.5	14	8.25
7			9	14.5	8.5
8			9.5	15	8.75
9			10	15.5	9
10			10	16	9.25
11			10	16.5	9.5
12			10	17	9.75


Edit

Delete


Extend



Displays a 12-Treatment Plan for the displayed patient.


5 Patient Exam Data


Patient, Sample (1234)

Status: **Active**
DOB: 7/5/1986
Provider: doctor



3/24/2010
 Edit
 Delete

1/24/2010


Height (inches) 70
Weight (lbs) 160
Heart rate: 62
Blood pressure: 110 / 70

Stage of Spinal Degeneration
Stage I

Orthopedic Tests
☐ Bakody
☐ Cervical Compression
☐ Cervical Distraction
☐ DeKleyn
☐ Reverse Bakody
☐ Shoulder Depression

Trigger Points
☐ Digastric
☐ Lateral Pterygoid
☐ Masseter
☐ Medial Pterygoid

Notes
Chronic headaches have greatly reduced in both frequency and intensity

Additional Orthopedic Tests

Ranges of Motion
Cervical (Normal) Actual
▶ Flexion (50): 46
▶ Extension (60): 55
▶ Lt. Lat. Flexion (45): 43
▶ Rt. Lat. Flexion (45): 43
▶ Lt. Rotation (80): 74
▶ Rt. Rotation (80): 74

Neurologic Tests
Muscle (Normal) Actual
C5 (5/5): 5/5
C6 (5/5): 5/5
C7 (5/5): 5/5
C8 (5/5): 5/5
T1 (5/5): 5/5
Reflexes (Normal) Actual
C5 (2): 2
C6 (2): 2
C7 (2): 2
C8 (2): 2

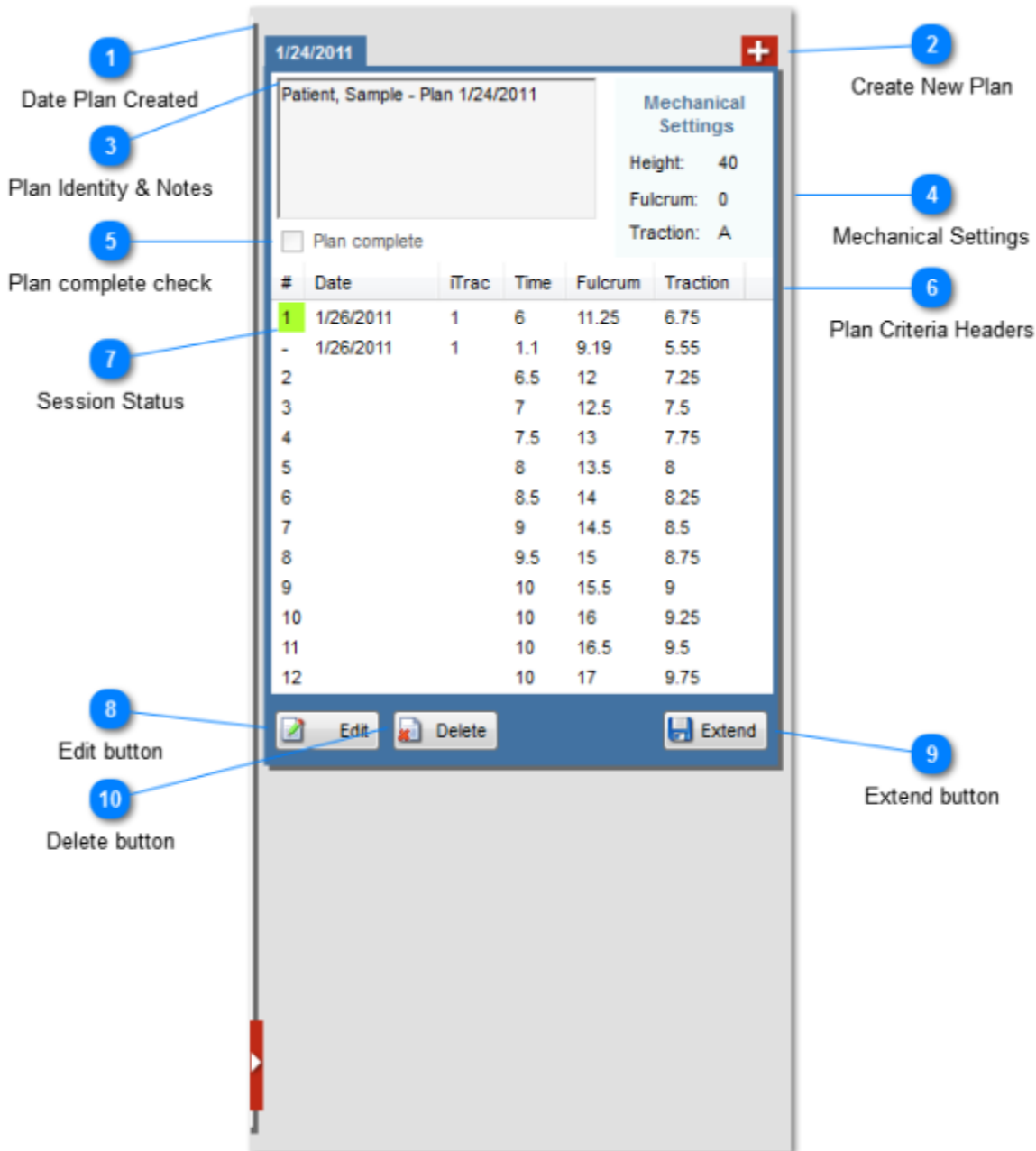
Neurologic Tests
Dermatomes
C2: Normal
C3: Normal
C4: Normal
C5: Normal
C6: Normal
C7: Normal
C8: Normal
T1: Normal

X-Ray Values
Lateral (Normal) Actual
Cervical Curve (42): 40
Fwd Head Post (0): 0
C1 Angle (29): 26
AP (Normal) Actual
TxH (0): 0
RzH (0): 0

Files
Images

6 System Status Display

Treatment Plan



1 Date Plan Created

2 Create New Plan

3 Plan Identity & Notes

4 Mechanical Settings

5 Plan complete check

6 Plan Criteria Headers

7 Session Status

8 Edit button

9 Extend button

10 Delete button

#	Date	iTrac	Time	Fulcrum	Traction
1	1/26/2011	1	6	11.25	6.75
-	1/26/2011	1	1.1	9.19	5.55
2			6.5	12	7.25
3			7	12.5	7.5
4			7.5	13	7.75
5			8	13.5	8
6			8.5	14	8.25
7			9	14.5	8.5
8			9.5	15	8.75
9			10	15.5	9
10			10	16	9.25
11			10	16.5	9.5
12			10	17	9.75

1 Date Plan Created

1/24/2011

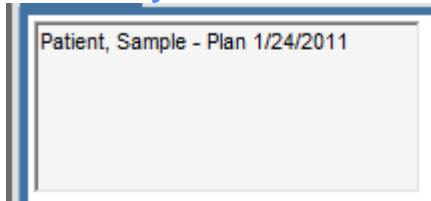
2 Create New Plan



Creates a new 12-session treatment as of today's date.

3

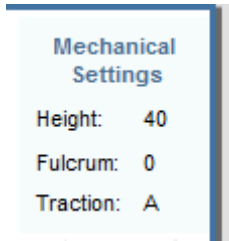
Plan Identity & Notes



System generated Plan Identity field displaying Patient and Date Plan Created
Additional space for textual notes.

4

Mechanical Settings



Mechanical Settings	
Height:	40
Fulcrum:	0
Traction:	A

Mechanical settings for displayed Patient and displayed Plan as prescribed by properly licensed practitioner.

5

Plan complete check

☐ Plan complete

Click to force Plan to "Complete" status regardless of remaining undelivered sessions.

6

Plan Criteria Headers

#	Date	iTrac	Time	Fulcrum	Traction

- Session # - Identifies Sessions 1 - 12 of the displayed Plan
- Date Delivered

- iTrac Unit delivered on
- Total Session Time
- Fulcrum Peak
- Traction Peak

7

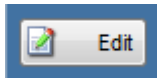
Session Status

#	Date	iTrac	Time	Fulcrum	Traction
1	1/26/2011	1	6	11.25	6.75
-	1/26/2011	1	1.1	9.19	5.55
2			6.5	12	7.25

- Session number highlighted = Session successfully delivered on displayed date
- Session number replaced with "-" = Session ended on displayed date prior to successful completion
- Session number normal = Session available for next use/delivery to patient

8

Edit button



Edit displayed plan

9

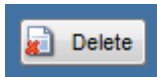
Extend button



Extend displayed plan

10

Delete button



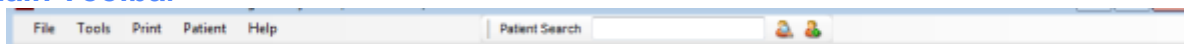
Delete displayed plan

Treatment Session



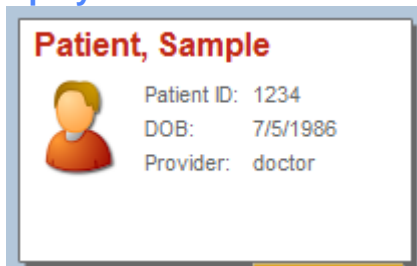
1

Main Toolbar



2

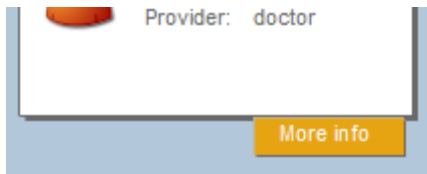
Displayed Patient Info



Displayed Patient Data

3

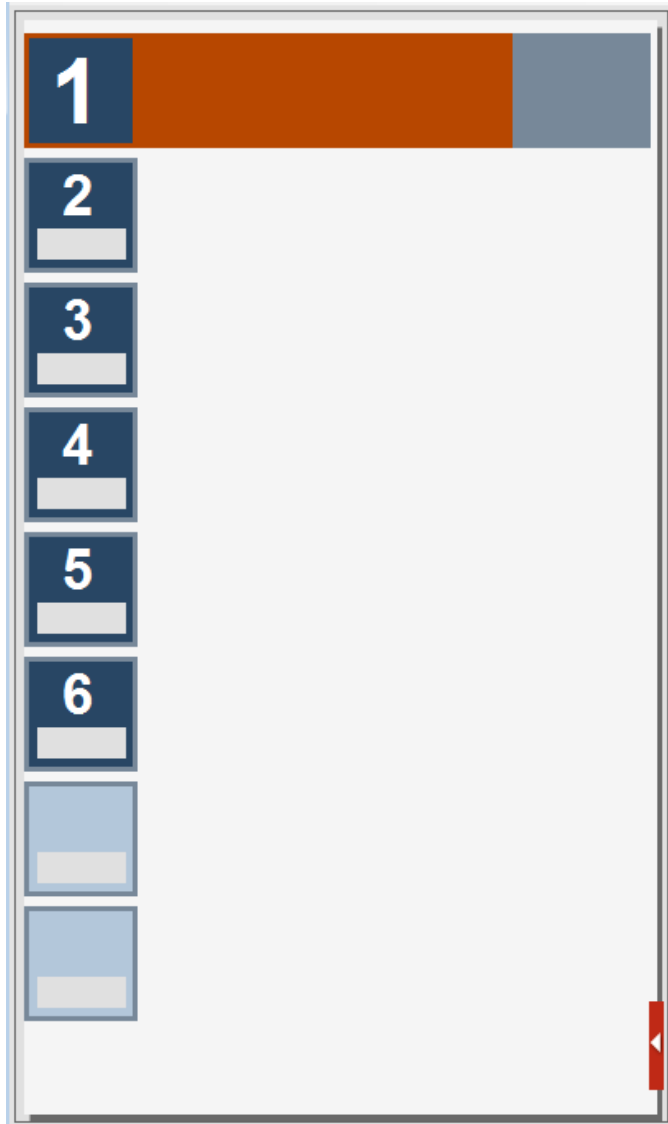
More Info button



When clicked, the displayed patient's exam data will be displayed.

4

iTrac Units



Displays the installed iTrac Units as numbered and vivid.
Displays positions available for installation of additional iTrac units as ghosted.

5

Session Progress Indicator



iTrac Unit #1 Treatment Progress indicator. (Note that this indicator begins the session colored green, then transitions toward red as the session progresses. The indicator advances to the right and also slowly transitions in color, finally displaying as fully red when the session nears completion (see below).



6

Hide/Show Treatment Plan



Click to Hide or Show the active Treatment Plan for the displayed Patient.

7

Active Displayed Session

Patient, Sample



Patient ID: 1234
DOB: 7/5/1986
Provider: doctor

More info



1

4:19 / 6:00

	Current	Peak
Traction (lbs)	6.7	6.75
Fulcrum (lbs)	11.17	11.25

Comments:

Enter comments here
Ease-Up Pressed

1:41





Patient Active Session window

8

Active Session Unit Assignment



iTrac Unit Session is running on

9

Session Time Values



Session Elapsed Time / Total Session Duration

10

Session Forces

	Current	Peak
Traction (lbs)	6.7	6.75
Fulcrum (lbs)	11.17	11.25

Session Current & Peak force values

11

Comments

Comments:

Enter comments here

Ease-Up Pressed

Enter comments here.

Note: If "Ease-Up" has been pressed at any time during the session, system will automatically add a comment to that effect in this box.

12

Session Controls

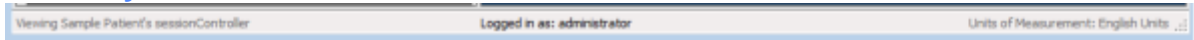


Displays (from left to right):

1. Session Time Remaining (count down)
2. Ease-Up button (reduces the current and peak Fulcrum & Traction forces each by 0.25 pounds, 1.11 Newtons or 0.11 kg depending on which Units of Measurement the User has selected.
3. Pause button places the current session in Pause mode, suspending all activity. The session can only be resumed by long-pressing the button located on the iTrac unit.
4. Stop button stops the current session and marks it in the Patient Treatment Plan as having being terminated prior to completion.

13

Current System Status



- Far left section displays current activity
- Center section displays "Logged In As:"
- Far right section displays currently selected Units of Measurement

14

Time Remaining in Session



Displays Minutes:Seconds

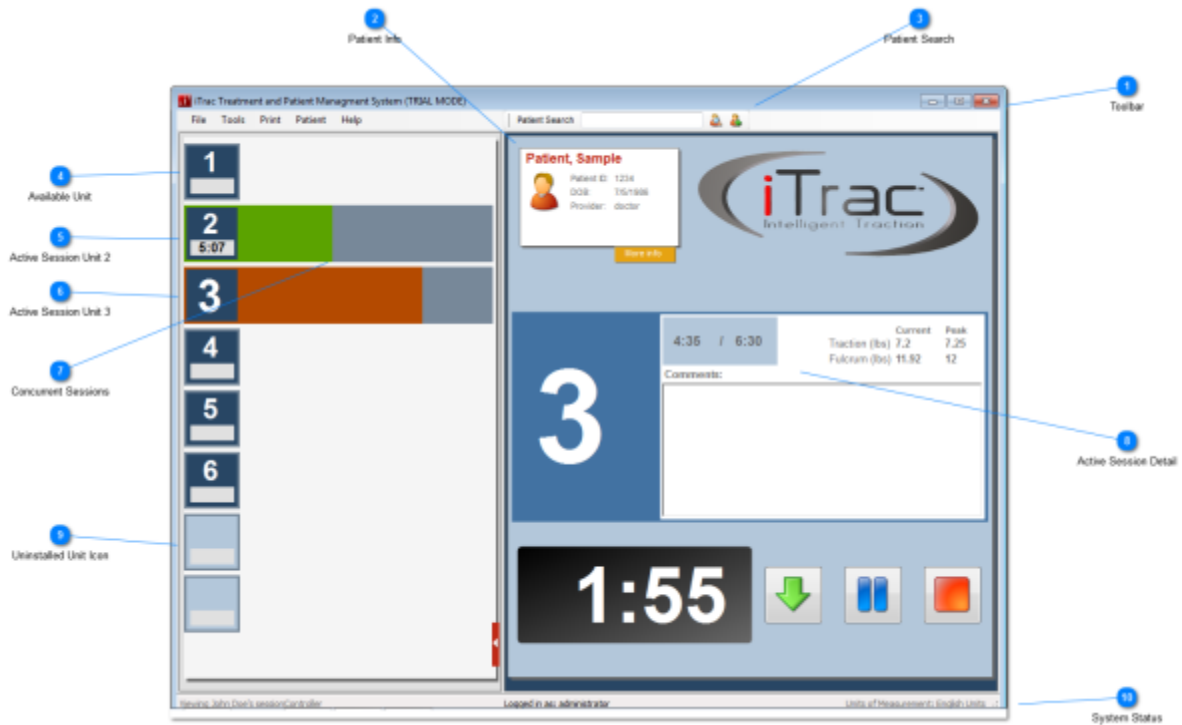
15

Ease-Up Button



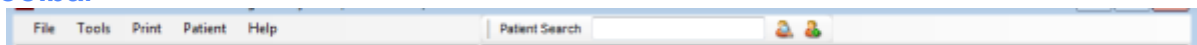
Ease-Up button (reduces the current and peak Fulcrum & Traction forces each by 0.25 pounds, 1.11 Newtons or 0.11 kg depending on which Units of Measurement the User has selected.

Concurrent Sessions



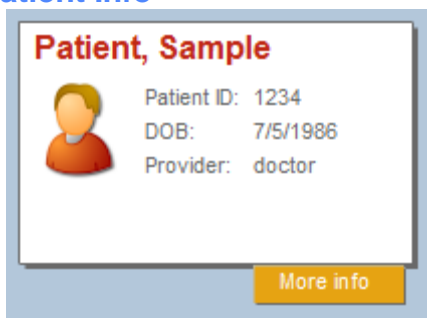
1

Toolbar



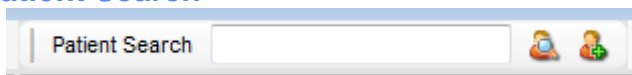
2

Patient Info



3

Patient Search



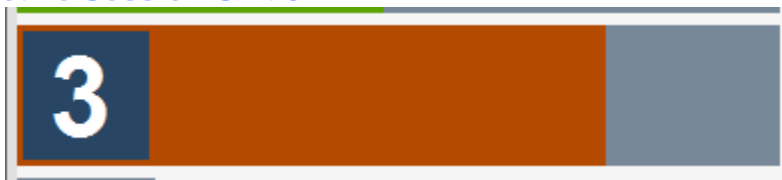
4 Available Unit



5 Active Session Unit 2



6 Active Session Unit 3



7 Concurrent Sessions





- The system will conduct unique sessions to as many as (8) individual patients concurrently.
- All active sessions will be displayed in the left Units Panel.
- Clicking on the Unit icon of any active session will display its details in the right Session Panel.



8

Active Session Detail

Patient, Sample

 Patient ID: 1234
 DOB: 7/5/1986
 Provider: doctor
[More info](#)






3

4:35 / 6:30

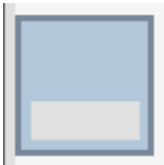
	Current	Peak
Traction (lbs)	7.2	7.25
Fulcrum (lbs)	11.92	12

Comments:

1:55

9 Uninstalled Unit Icon

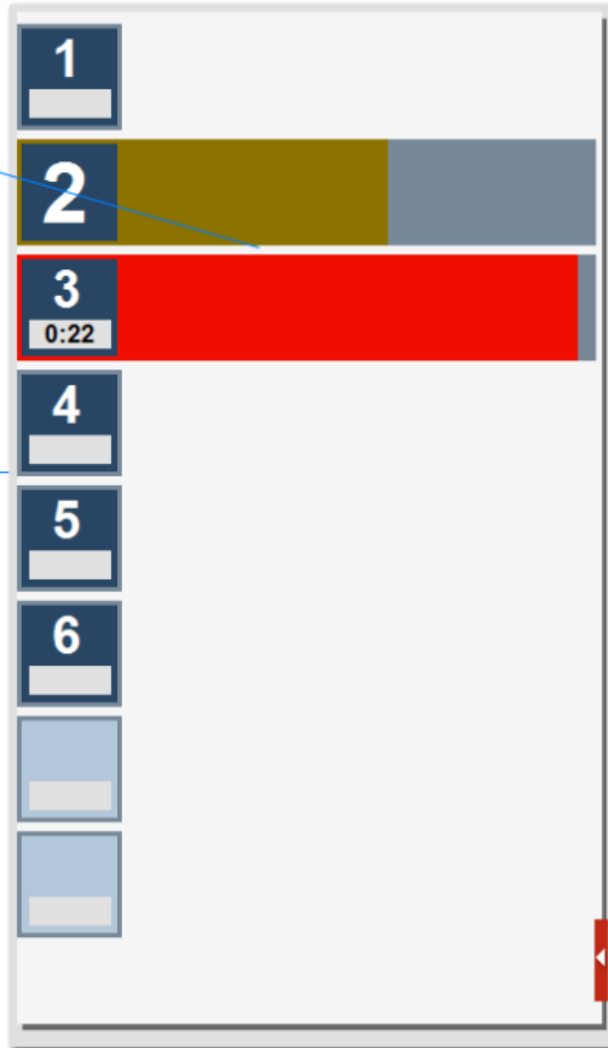


10 System Status

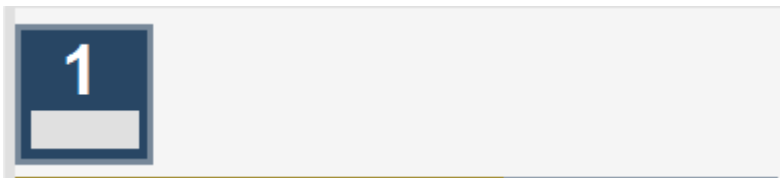
Viewing John Doe's sessionController Logged in as: administrator Units of Measurement: English Units

End of Session

- 1 Installed Unit 1
- 6 Concurrent Sessions on 2 & 3
- 2 Unit 2 in Session
- 3 Unit 3 Nearing Session End
- 4 Installed Unit 4
- 5 Installed Unit 5



1 Installed Unit 1



This Unit has no session active at this time.

2 Unit 2 in Session



Progress bar slowly transitioning from green toward red.

3

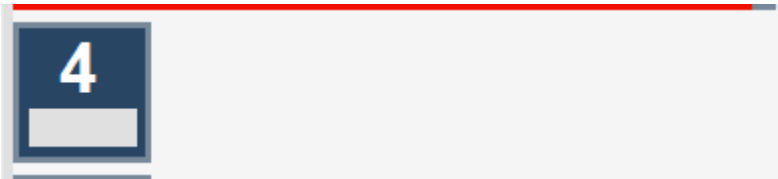
Unit 3 Nearing Session End



Progress bar red and nearing end of session (22 seconds remaining).

4

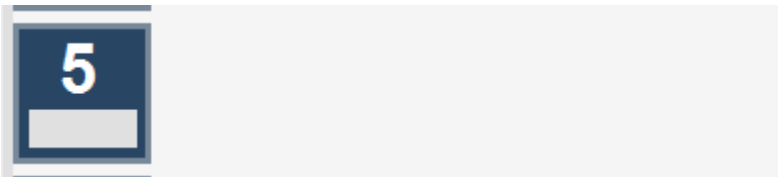
Installed Unit 4



This Unit has no session active at this time.

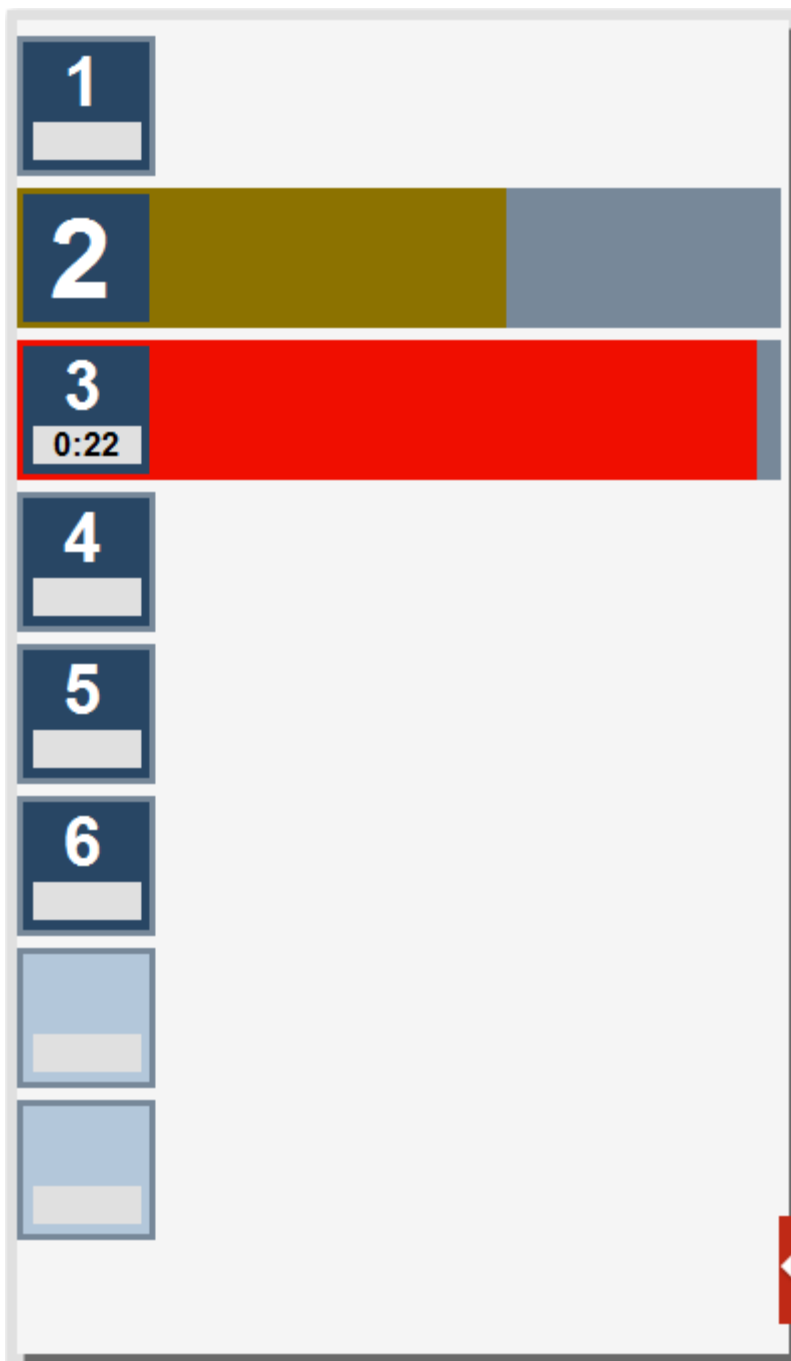
5

Installed Unit 5



6

Concurrent Sessions on 2 & 3



A) Preparing the Treatment

- 1) Select the correct patient record in the iTrac software Search window.



- 2) Once the correct patient record displays, move the cursor to the patient's name. Now left click and continue holding down the left mouse key on the patient's name, and drag the patient's name to the correct icon matching the desired iTrac machine. The selected patient's next successive treatment is now automatically loaded and waiting at that selected machine, indicated by a slow blink of the green Treatment LED on the selected machine.

B) Machine Setup

- 1) Raise or lower the central column to obtain the numerical setting to properly align the fulcrum cushion strap with the physician prescribed target region of the posterior cervical spine.
- 2) Adjust the Fulcrum Angle to a setting that aligns the Fulcrum cushion strap with the physician prescribed target region of the cervical spine.
- 3) Adjust the Traction angle to the prescribed alphabetical setting to properly align the angle of Traction.

C) Positioning the Patient

- 1) Assist the patient to a fully seated position in the iTrac seat. Their back should be in comfortable contact with the seat back and their posterior neck region should be resting against the fulcrum cushion strap.
- 2) Place the Patient Stop Switch in the patient's hand, explain its function and verify that the patient understands your explanation by asking them to demonstrate pressing the Patient Stop Switch.

D) Connecting the Traction Line & Positioning the Headgear

- 1) Attached the headgear to the traction line using the magnet-release coupler. It is important to properly align the magnets to maintain good a connection. Note: The magnet-release is an important safety feature intended to free the patient in the event of excessive force. **Never remove the magnet or attempt to attach the traction line directly to the headgear.**
- 2) Holding the headgear, withdraw the traction line from its port and place the headgear over the patients head with the FRONT label oriented to the patient's face and the BACK label oriented to the posterior portion of the patient's head.
- 3) If desired, a spreader bar may be used.



- 4) Adjust the headgear side straps as needed by securing the hook and loop fasteners in the desired position. As a guideline, the headgear should be adjusted to comfortably fit the size & shape of the patient's head for treatments.

E) Initiating the Treatment

- 1) Verify that the patient has the Stop Control in their hand and that they are properly instructed on its use.
- 2) With the patient's neck just touching the Fulcrum Cushion Strap, move the Traction Line control to the Lock position.
- 3) Verify that the patient is ready for the treatment to commence, and then press the Treatment pushbutton switch (located on the control console) for 1 second to initiate treatment. The green Treatment LED will change from its previous slow blink to a steady ON condition, indicating that the treatment is in progress.

F) Pausing & Resuming the Treatment

- 1) To pause the treatment for any reason, press the pause pushbutton switch for 1 second. The treatment will pause and the green Treatment LED will begin a slow blink, indicating the paused condition. All air pressure will immediately be relieved, removing all forces from the patient.
- 2) To resume the treatment, press the Treatment pushbutton switch for 1 second. The green Treatment LED will change from its previous slow blink to a steady ON condition, indicating that the treatment is again in progress.

G) Completing the Treatment

- 1) The iTrac software will automatically cease the treatment once it is completed.
- 2) Move the Traction Line control to the Unlock position. Grasp the Traction line snap and carefully unsnap it from the headgear (or spreader bar, if used). Allow the retrieval system to retract the Traction line snap back into its port.
- 3) Assist the patient in regaining a head-centered upright position by supporting their head as they bring it back into a normal upright position.
- 4) Assist the patient as they stand to exit the device.
- 5) Clean all patient contact surfaces as required by clinic & regulatory protocol.



Section III- Treatment Example

For this example, a patient with a hypolordotic cervical spine and concurrent forward head posture will be treated with extension traction. Prior to the patient treatment series beginning, the traction settings are determined using x-ray analysis of the patient's cervical spine. For this example the patient's cervical curve loss is greatest at the C3 and C4 levels and the forward head posture measures 30mm. With the iTrac set to the specific settings for this patient, seat the patient in the chair.

Continue patient set up following the instructions in Section II. For such a condition as described above, a series of 12 treatments is typical. The initial treatment (Treatment #1) will be 5 minutes in duration. It will achieve a fulcrum (front pull) peak force of 18 lbs and a traction (back pull) peak force of 8 lbs. In this example, the doctor has prescribed and instructed the iTrac software to automatically add 1.0 minute to subsequent treatment duration. He has also instructed the software to automatically add 1.0 lbs of fulcrum peak force and .5 lbs of traction peak force to each subsequent treatment only until a maximum of 15 minutes duration, 29 lbs fulcrum peak force and 13.5 lbs traction peak force are reached. At this point the time and peak force settings remain the same for the rest of the treatments in the series.

Treatment #	Time (Duration)	Peak Fulcrum Force	Peak Traction Force
1	5 minutes	18.0 lbs.	8.0 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
2	6 minutes	19.0 lbs.	8.5 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
3	7 minutes	20.0 lbs.	9.0 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
4	8 minutes	21.0 lbs.	9.5 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
5	9 minutes	22.0 lbs.	10.0 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
6	10 minutes	23.0 lbs.	10.5 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
7	11 minutes	24.0 lbs.	11.0 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
8	12 minutes	25.0 lbs.	11.5 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
9	13 minutes	26.0 lbs.	12.0 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
10	14 minutes	27.0 lbs.	12.5 lbs.
Increases	1 minute	1.0 lbs.	0.5 lbs.
11	15 minutes	28.0 lbs.	13.0 lbs.
Increases	None	1.0 lbs.	0.5 lbs.
12	15 minutes	29.0 lbs.	13.5 lbs.
Treatment Series Complete			

The Pause feature of the iTrac allows the operator to adjust the treatment time and force midway through the treatment. When a treatment session is complete, follow instructions in Section II to assist patient in exiting the device. There is no single "recipe" for success. These are general treatment principles and should be adjusted individually for each patient as needed. Monitor the patient closely on the first



treatment and on all subsequent treatments.

Section IV – Software: *Installation, Setup & Operation*

The computer supplied with the iTrac unit is for use only with the iTrac unit. Networking and internet access has been disallowed by blocking inbound and outbound traffic other than that to the iTrac device from within the Windows firewall. This is to prevent any misuse, cybersecurity concerns, and damage from viruses. The administrator shall not try to circumvent these safety precautions.

Dedicated Device: Administrator Responsibility

It is the responsibility of the Administrator to maintain the computer supplied with iTrac system, on which the iTrac software is installed, as a dedicated machine, running ONLY the iTrac software.

Isolated Device: Administrator Responsibility

It is the responsibility of the Administrator to maintain the computer on which the iTrac software is installed as an isolated machine, not connected to any intranet, internet or other non-iTrac network.

Device Security: Administrator Responsibility

It is the responsibility of the Administrator to maintain a secure environment for the iTrac software and hardware.

Device Physical Security: Administrator Responsibility

It is the responsibility of the Administrator to maintain a secure environment for the iTrac software and hardware.

Protected Health Information (PHI) Security: Administrator Responsibility

It is the responsibility of the Administrator to maintain a secure environment for all Protected Health Information associated with the iTrac software and hardware. Should it become necessary for an authorized non-employee service technician to access the software or hardware for repairs, adjustments or other field service tasks, it is recommended that the Administrator create a “dummy” patient record and make ONLY that “dummy” patient record available to the technician for diagnostic and testing purposes.

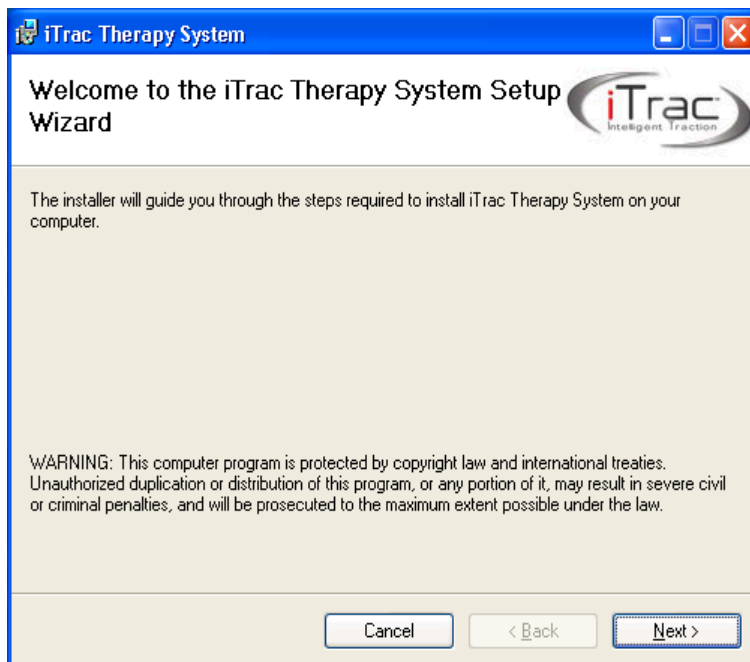
Software *INSTALLATION*: Microsoft SQL Server-Administrator Responsibility

Refer to the latest Microsoft SQL Server Software installation instructions on the Microsoft website.

Software *INSTALLATION*: iTrac- Administrator Responsibility

This section defines the **INSTALLATION** of the iTrac Software on a Windows computer dedicated to its operation. Each of the screens is illustrated and explained below.

1. Insert the iTrac Program Distribution disk into the appropriate drive on your computer.
2. The self-executing installer window will appear. If you are ready to continue the installation of the iTrac software, follow the on-screen instructions.
3. Welcome Screen

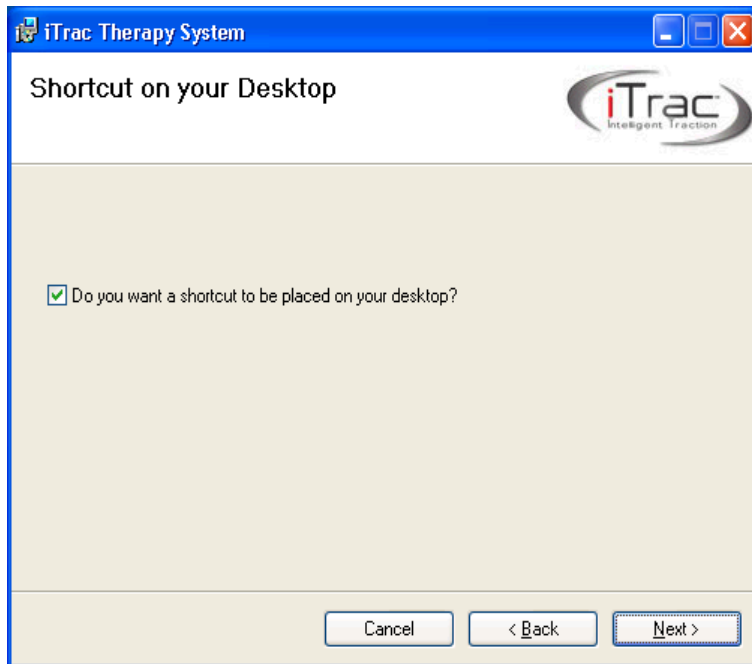


4. License Agreement
 - a. **Administrator Responsibility:** Read the end-user license agreement for the iTrac Therapy System. If you agree select the I agree radio button then click next. If you do not agree select the I Do Not Agree radio button. The software installation will end without installing.

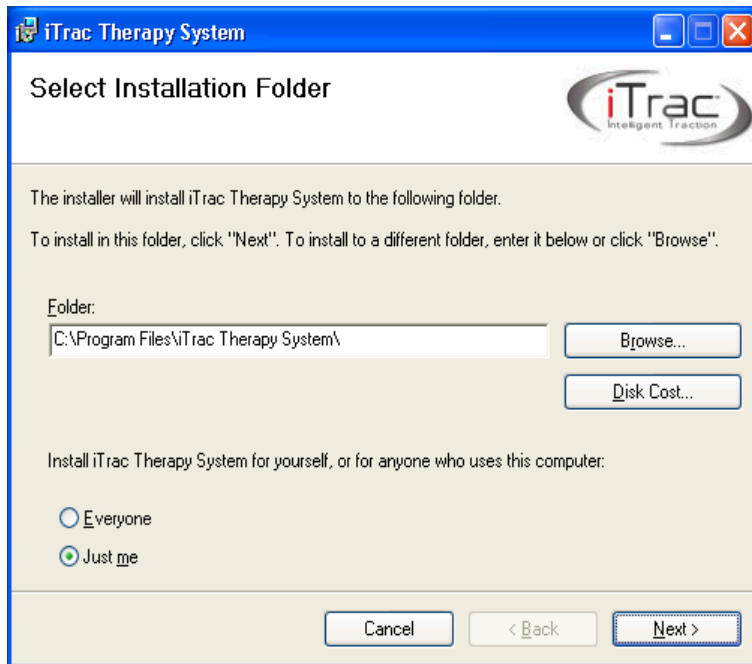


5. Desktop Shortcut.

- a. If you would like a shortcut placed on your desktop during installation leave the check in the "Do you want a shortcut to be placed on your desktop?" and click next.
- b. If you do not want a shortcut placed on your desktop during installation remove the check in the "Do you want a shortcut to be placed on your desktop?" and click next.



6. **Administrator Responsibility:** Select Installation Folder
 - a. If you would like the program installed in "C:\Program Files\iTrac Therapy System\" leave the default.
 - b. If you would like the program to be installed in a location other than "C:\Program Files\iTrac Therapy System\" click the browse and select the desired folder.
 - c. If you would like the iTrac Therapy System software available to just you select the "Just me" radio button.
 - d. If you would like the iTrac Therapy System software available to everyone select the "Everyone" radio button.
 - e. Click next.

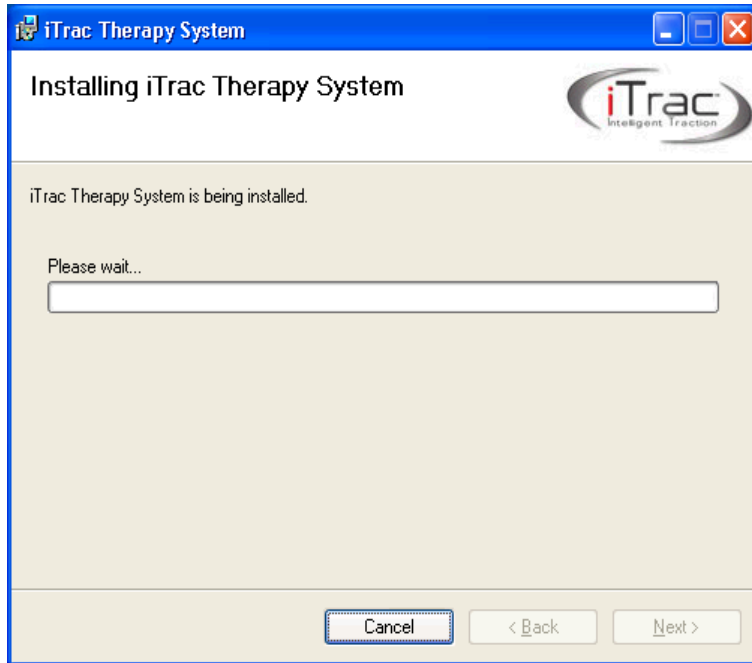


7. **Administrator Responsibility:** Confirm Installation
 - a. Once all parameters have been entered press the next button. If you would like to change any parameters press the back button.



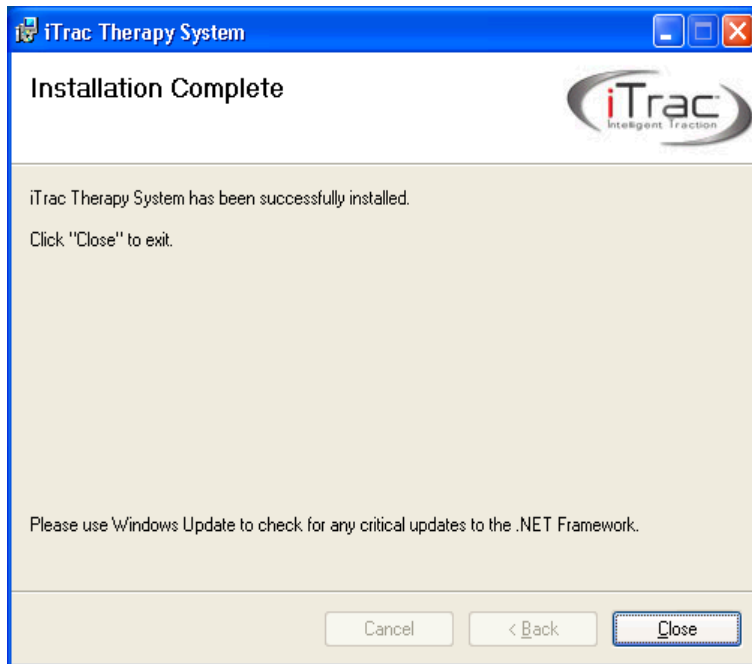
8. Installation Screen

- a. After pressing the next button the Installing iTrac Therapy System screen opens and the files are installed onto the computer.



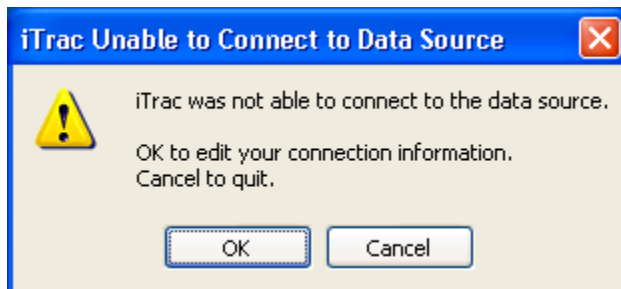
9. Installation Complete

- a. After the files have been installed the installation complete screen appears. Clicking on the close button will complete the installation and close the screen.



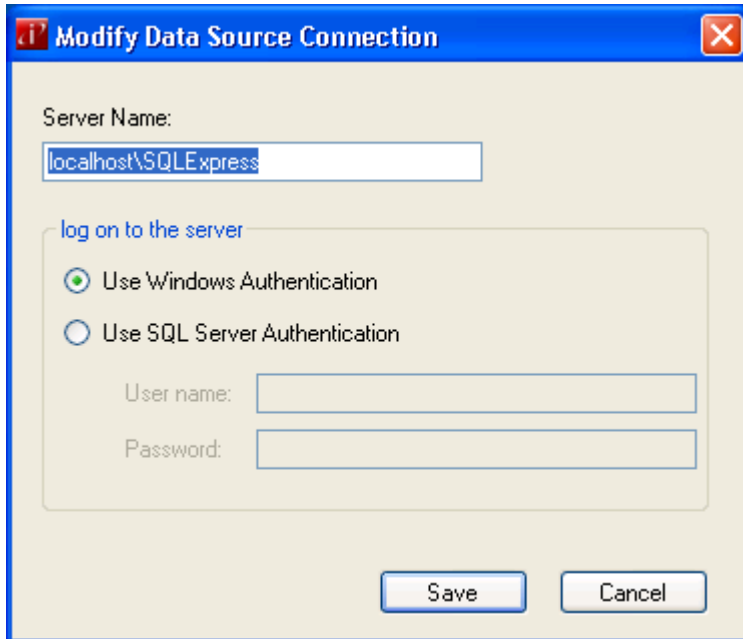
10. iTTrac Unable to Connect to Data Source

- a. If the software is not able to find the SQL database this error will appear.
- b. Clicking the OK button will allow you to edit the location of the database.



11. **Administrator Responsibility:** iTTrac Modify Data Source Connection screen will appear after clicking ok.

- a. If the location of the SQL database is somewhere other than the default location enter that path in the server name field.
- b. If the User authentication is something other than windows authentication select Use SQL Server Authentication and enter the User name and Password.

A Windows-style dialog box titled "Modify Data Source Connection". It has a blue title bar with a close button. The main area is light beige. It contains a "Server Name:" label followed by a text box containing "localhost\SQLEXPRESS". Below this is a section titled "log on to the server" with two radio buttons: "Use Windows Authentication" (selected) and "Use SQL Server Authentication". Under the "Use SQL Server Authentication" option are two text boxes labeled "User name:" and "Password:". At the bottom are "Save" and "Cancel" buttons.

Server Name:

localhost\SQLEXPRESS

log on to the server

☒ Use Windows Authentication

☐ Use SQL Server Authentication

User name:

Password:

Save Cancel

12. **Administrator Responsibility:** You will be asked to supply a unique key code to complete the installation. This key code will be supplied to you by Pivotal Health Solutions, Inc. at the time of purchase.

A Windows-style dialog box titled "Registration Form". It has a blue title bar with minimize, maximize, and close buttons. The main area is light beige. It contains the text: "If you don't already have a license key or would like to purchase more licenses, contact your iTrac sales rep." Below this is a label "License Key:" followed by the text "Invalid or Incomplete" in red. There are four empty text boxes for the license key. Below these are two labels: "# Licenses Purchased:" and "# Licenses Used:", each followed by a text box containing the number "0". At the bottom are "Cancel" and "Register" buttons.

Registration Form

If you don't already have a license key or would like to purchase more licenses, contact your iTrac sales rep.

License Key: Invalid or Incomplete

Licenses Purchased: 0

Licenses Used: 0

Cancel Register

13. The software will now complete the installation process.



Software *USER SETUP*: *Administrator Responsibility*

This section defines the SETUP of the iTrac Software on your Windows computer.

1. The default Username is “administrator” and the default Password is “iTrac4life”
2. Persons accessing the software via an “administrator” level login will have full access to all features and functions of the program. This highest level of access allows the administrator-level user to:
 - a. Add, delete & modify users and user permissions.
 - b. Add, delete & modify patient records.
 - c. Add & delete patient examinations.
 - d. Add, delete & modify images connected to any patient’s record.
 - e. Add, delete & modify documents connected to any patient’s record.
 - f. Modify Plan Default settings, IP address ranges, Registration information and all other settings in the Options group.
3. **NOTE:** With the purchase of the software, the administrator accepts responsibility for compliance with all patient privacy and professional accountability requirements as impacted, controlled, affected or otherwise influenced by this software.
4. To enable the highest level of control over these important areas, the software provides multiple levels of access based on user type and granted privileges. These levels and their levels of access are:
 - a. **Administrator** – full access & control
 - b. **Doctor** – full access to all features EXCEPT “Add User”
 - c. **Assistant** – access limited only to Add Patient, Administer Treatment, Print Reports, Manage Images, Manage Documents
5. To add additional users and set their respective levels of control, the administrator will utilize the following process:
 - a. To add a new user with limited privileges:
 - i. Tools> Manage Users> Add User
 1. **Username:** create a unique username for this user.
Example: “drsmith” with Dr. Smith being one of the clinic’s providing doctors
 2. **Password:** create a unique password for this user.
 3. Confirm Password: re-enter the newly created password for validation.
 4. **Email:** enter a valid email for this user.
 5. **Role:** select the appropriate role from the drop-down list: “administrator”, “assistant” or “doctor”
 6. Once all fields are correctly completed, click Add and the new user will be completed.
 7. As many users as required can be added at each Role



level.

Software *USER OPTIONS*

This section defines the USER OPTIONS available in the iTrac Software on your Windows computer.

1. There are User Options available to customize the iTrac software to your practice. To access these options select the menu choice TOOLS> OPTIONS> The following steps will instruct you on each available tab in this menu.
2. THEMES: Choose a screen color theme from the available options or create, name and save your own custom theme.
3. PLAN DEFAULTS: **Access to PLAN DEFAULTS is software-constrained ONLY to Users having ADMINISTRATOR or DOCTOR credentials.** The Plan Defaults are those values that the software automatically uses to create each new patient's initial treatment plan. You may use this screen to modify those default values for all future new treatment plans.
4. iTrac UNITS: This screen allows you to modify the default IP addresses where the systems searches for connected iTrac units.
5. REGISTRATION: Use this screen to enter your professional and practice information for use in reporting, etc.
6. OTHER:
 - a. This screen allows you to modify the use of a software-initiated tone to mark the approaching end of a treatment session.
 - b. This screen also allows you to determine when or if you wish to be notified that a patient's 12-treatment series is nearing completion.

Software *OPERATION*

This section defines the OPERATION of the iTrac Software for the Pivotal Health Solutions, Inc. iTrac.

1. To begin using the software, select the iTrac program icon from your Desktop or from your Start> Programs icon. The iTrac Login window will appear.
2. Enter your Username and Password (registered users only) and click OK or press Enter. The program will advance to the iTrac Treatment and Patient Management System screen.
3. Place the cursor in the Patient Search box and begin typing a few letters of the person's first or last name. All patients matching the typed characters will immediately be displayed, allowing you to select the correct patient by clicking on their name from the displayed list.
4. The selected patient's basic information will now be prominently displayed. To

- display detailed examination, image and document information for this patient, click the More Info button.
5. To prepare the next successive treatment for the selected patient, click and drag that patient's name on to the numbered iTrac machine icon corresponding to the machine you wish to deliver the treatment with. (These icons are located near the left border of the iTrac software window.)
 6. The treatment for the selected patient is now prepared and paused on the selected machine. This paused or suspended condition is indicated by a slow blink of the green Treatment LED on that specific machine.
 7. For specific instructions on how to begin the treatment, see Section II of this document.



Menu specifications

Click Menu> File – System displays File options

Hover Menu> File> New – The system displays clickable New Patient and New Unit choices

Click Menu> File> New> Patient – The system displays the New Patient Screen which contains:

Name – The User is allowed to enter the Patient Name in “Firstname” “space” “Lastname” format

Patient ID – The User is allowed to enter a unique Patient ID in alphanumeric characters. If no entry is made, system assigns a unique random alphanumeric Patient ID

Click Gender – The User is allowed to click Male or Female

Click Save – The system saves the newly added patient record to the relational database

Click Cancel – The system closes the New Patient screen

Date of Birth – The User is allowed to enter the patient birth date in MM/DD/YYYY format

Provider – The User is allowed to enter the provider’s (Doctor’s) name or to select the provider from the dropdown list

Click Inactive – The User is allowed to click to mark this patient as inactive

Number of Patients Limited in TRIAL Mode - If (5) unique patient records exist in database, and User attempts to add new patient while software is running in Trial Mode, the system displays an error screen: Cannot Add Patient "Cannot add a new patient. If in trial mode, please purchase



a valid license and enter key into the Registration form in the Tools menu."

Click Menu> File> New> Unit – The system displays the Add Unit screen which contains:

Unit Number – The User is allowed to select the desired unassigned Unit number to be assigned to the new unit being added

Description – The User is allowed to enter a description of the new unit being added

MAC Address – The User enters the hexadecimal MAC (Media Access Control) address of the new unit being added

IP Address – The User may enter the IP address of the new unit being added

Click OK – The system adds the new unit to the relational database and creates a Unit icon

Cancel – The system closes the Add New Unit screen

Click Menu> File> Exit – The system closes the software application

Click Menu> Tools> Locate Units – The system displays the Locate Units Screen which contains:

Unit Information – The system displays the Unit Numbers, Descriptions and IP Addresses for all currently assigned units

Progress Complete – The system displays the progress of locating units

Click Locate Units – The system executes the Locate Units routine

Click Close – The system closes the Locate Units screen

Click Menu> Tools> Modify Data Source Connection – The system displays the Modify Data Source Connection screen which contains:

Server Name – The User is allowed to enter the data source server name

Click Log on to the Server> Use Windows Authentication – The system accepts Windows Authentication as the chosen method of logging on to the server. The required login username and password provide security for all application database files and are to be managed and provided by the Administrator.

Click Log on to the Server> Use SQL Server Authentication - The system accepts SQL Server Authentication as the chosen method of logging on to the server. The required login username and password provide security for all application database files and are to be managed and provided by the Administrator.

User Name – The User is allowed to enter the username for SQL Server authentication

Password – The User is allowed to enter the password for SQL Server authentication

Click Save – The system saves changes

Click Cancel – The system closes the Modify Data Source screen

**Click Menu> Tools> Manage Users (visible only to Administrator-level User)
– The system displays the Manage Users screen which contains:**

User Information – The system displays the User, Role and Email for all currently valid Users

Right Click or Double Click Individual User Information row – The system opens list of options: Add User, Modify User, Delete User, Reset Password

Click Add User menu item – The system displays the Add User screen (Ref. 3.5.8.3.)

Click Modify User – The system displays the Modify User screen for the selected User

Click Delete User – The system displays the Challenge screen in regard to the deletion of the selected User

Click Reset Password – The system generates a new password for the selected user, then display a Success screen showing the new password



Click Add User button – The system displays the Add User screen which contains:

Username – The User enters a unique username consisting of alphanumeric characters

Password – The User enters a unique password consisting of alphanumeric characters

Confirm Password – The User re-enters the unique password. The system validates that it matches the value entered in the Password field

Full Name – The User enters a unique full name, typically in one of these formats: Dr. John Doe; Mary Smith

Email – The User may enter an email address for the New User

Role – The User selects the correct Role for the New User

Click Add – The system adds the newly created User to the relational database

Click Cancel – The system closes the Add User screen Click Close – The system closes the Manage Users screen

Click Menu> Tools> Manage My Profile – The system displays the Modify User screen for the currently logged in User. The Modify User screen contains:

Username – The system displays the current username

Full Name – The current User is allowed to modify their Full Name

Email – The current User is allowed to modify their email

Role – The system displays the Role of the current User

Click Change Password – The system displays the Change Password screen which contains:

Old Password – The User enters their Old password

New Password – The User enters their desired, unique New password

Confirm Password – The User re-enters their desired, unique New password.



Click Change – The system replaces the Old password with the New password in the relational database for the current User

Click Cancel – The system closes the Change Password screen

Click Modify – The system updates the relational database record for the currently logged in User with the requested modifications

Click Cancel – The system closes the Modify User screen

Click Menu> Tools> Options – The system displays the Options screen which contains clickable Themes, Plan Defaults Units, Contact Info and Other tabs. When clicked by the User, each displays a corresponding sub-screen as follows:

Options/Themes sub-screen contains:

Name – User selects either existing Theme name or Create New Theme

Description – User may enter a description of the theme

Colors – User may click to select specific colors for all regions of software screens

Click OK – The system saves the modifications to the selected theme and apply that theme to the software screens

Click Cancel – The system closes the Options screen

Click Apply – The system applies the modified theme settings to the software screens

Options/Plan Defaults sub-screen contains:

Starting Time – The Administrator or Doctor-level user may alter the Treatment default Session Starting Time value

Starting Fulcrum – The Administrator or Doctor-level user may alter the Treatment default Session Starting Fulcrum value

Starting Traction – The Administrator or Doctor-level user may alter the Treatment default Session Starting Traction value



Increment Time – The Administrator or Doctor-level user may alter the Treatment default Session Increment Time value

Increment Fulcrum – The Administrator or Doctor-level user may alter the Treatment default Session Increment Fulcrum value

Increment Traction – The Administrator or Doctor-level user may alter the Treatment default Session Increment Traction value

Peak Time – The Administrator or Doctor-level user may alter the Treatment default Session Peak Time value

Peak Fulcrum – The Administrator or Doctor-level user may alter the Treatment default Session Peak Fulcrum value

Peak Traction – The Administrator or Doctor-level User may alter the Treatment default Session Peak Traction value

Standard Progression – The system displays a graphic representing the standard progression of a Treatment Session

Click OK – The system updates all Plan Default values to the relational database

Click Cancel – The system closes the Plan Defaults screen

Click Apply – The system applies all updated Plan Default values

Options/Units sub-screen contains:

Start IP Address – The User may alter the starting IP address of the range to be searched

End IP Address – The User may alter the ending IP address of the range to be searched

Click OK – The system updates the IP search range with the new values and then close the Options screen

Click Cancel – The system closes the Options screen

Click Apply – The system updates the IP search range with the new IP address values



Options/Contact Info sub-screen contains:

Practice - The User may alter the Practice name

Mailing Address - The User may alter the Practice mailing address

Phone - The User may alter the Practice phone number

Email - The User may alter the Practice Email address

Web Address - The User may alter the Practice web address

Click OK – The system updates the record with the new values and then close the Options screen

Click Cancel – The system closes the Options screen

Options/Other sub-screen contains

Sounds: Play sound when (??) Minutes remain in Treatment Session – The User may modify when the system plays a tone in relation to the end of a treatment session

Sounds: Click All Sounds Off – The system plays no sounds

Notifications: Notify Treatment Plan "Near Completion" when (??) Sessions remain – The User may modify the number of uncompleted treatment sessions that should remain in a specific treatment plan before the system displays the "Treatment Plan Near Completion" popup notification screen

When Notify Treatment Plan Near Completion is active and when plan reaches User defined Number of uncompleted sessions remaining, system displays: "Nearing end of treatment plan, consider a re-exam for (system inserts active Patient Name)."

Notifications: Click "Near Completion" notification OFF – The system will not display the "Treatment Plan Near Completion" popup notification screen

Units of Measurement: Click to select desired Unit of Measurement (English Units, SI Units, Metric Units) – The system displays all length & weight field values in the selected system of units

Click OK – The system updates the Other fields with the changed values and then closes the Options screen

Click Cancel – The system closes the Options screen



Click Apply – The system updates the original Other values with the changed Other values and the Other screen remains open

Click Menu> Tools> Register – The system displays the Registration Form screen which contains:

License Key – User enters valid License Key.

Number of Licenses Purchased – Upon user entry of a valid license key (above), the system displays the number of licenses purchased

Number of Licenses Used – Upon user entry of a valid license key (above), the system displays the number of licenses currently installed (in use)

Click Cancel – The system closes the Registration Form screen

Click Register – The system registers and activates the software in accordance with the license purchased. (Note: The system displays the



Register key as inactive [grayed out] unless the User has entered a valid license key [see Registration].)

Click Menu> Print> Print Progress Report – The system displays the Progress Report screen which contains:

Initial Exam – The User selects an Initial Exam date for the Progress Report

Initial Image – The User selects an Initial Image file for the Progress Report

Progress Exam – The User selects a Progress Exam date for the Progress Report

Progress Image – The User selects a Progress Image file for the Progress Report

Practice – The User may alter the displayed default Practice name

Address – The User may alter the displayed default Address

Click Preview – The system creates and display the Progress Report in Print Preview

Click Print – The system creates the Progress Report and open the Windows Print window

Click Cancel – The system closes the Progress Report screen

Click Menu> Print> Print Treatment Recommendation Report – The system displays the Treatment Recommendation Report screen which contains:

Exam – The User selects an Exam date for the Treatment Recommendation Report

Image – The User selects an Image for the Treatment Recommendation Report

Number of Treatments – The User selects a value corresponding to the number of treatments in the Doctor-prescribed Treatment Plan for the Treatment Recommendation Report



Treatments per Week – The User selects a value corresponding to the number of treatments per week in the Doctor-prescribed Treatment Plan for the Treatment Recommendation Report

Treatments will include – The User selects the Doctor-prescribed therapies and/or manipulations for the Treatment Recommendation Report

Home Care Recommendations – The User selects the Doctor-prescribed home care recommendations for the Treatment Recommendation Report

Click Custom Treatments – The system displays the Custom Treatments description box in a state allowing data entry

Custom Treatment Description – The User enters descriptions for the Doctor-prescribed custom treatments for the Treatment Recommendation Report

Click Prescribed Home Exercises – The system displays the Custom Treatments description box in a state allowing data entry

Prescribed Home Exercises Description – The User enters descriptions for the Doctor-prescribed custom treatments for the Treatment Recommendation Report

Click Prescribed Home Stretches – The system displays the Custom Treatments description box in a state allowing data entry

Prescribed Home Stretches Description – The User enters descriptions for the Doctor-prescribed custom treatments for the Treatment Recommendation Report

Click Ergonomic Tips – The system displays the Custom Treatments description box in a state allowing data entry

Ergonomic Tips Description – The User enters descriptions for the Doctor-prescribed custom treatments for the Treatment Recommendation Report

Practice – The User may alter the displayed default Practice name

Address – The User may alter the displayed default Address



Click Preview – The system creates and display the Treatment Recommendation Report in Print Preview

Click Print – The system creates the Treatment Recommendation Report and open the Windows Print window

Click Cancel – The system closes the Treatment Recommendation Report screen

Click Menu> Patient – System displays Patient options

Hover Menu> Patient> New – The system displays clickable New Exam and New Plan choices

Click Menu> Patient> New> Exam – The system displays the New Exam screen which contains the following fields and information. NOTE: This data is used primarily for historical, report-generating and record-keeping purposes and is not used in any treatment-related processes or



calculations. The Doctor creates his/her professional diagnosis of the patient's condition(s).

Exam Date – The system displays the system date in MM/DD/YYYY format. The User is allowed to modify the Exam Date

Height – The User is allowed to enter a value

Weight – The User is allowed to enter a value

Heart Rate – The User is allowed to enter a value in Beats per Minute (BPM)

Blood Pressure (systolic) – The User is allowed to enter a value

Blood Pressure (diastolic) – The User is allowed to enter a value

Stage of Spinal Degeneration – The User is allowed to select one Stage of Spinal Degeneration from the system-supplied list

Trigger Points – The User is allowed to select one or more Trigger Points from the system-provided list

Orthopedic Tests – The User is allowed to select one or more Orthopedic Tests from the system-supplied list

Notes – The User may enter text provided by the Doctor

Additional Orthopedic Tests – The User may enter text describing additional orthopedic tests performed by the Doctor

Ranges of Motion: Cervical Flexion – The User may enter a value

Ranges of Motion: Cervical Extension – The User may enter a value

Ranges of Motion: Cervical Left Lateral Flexion – The User may enter a value

Ranges of Motion: Cervical Right Lateral Flexion – The User may enter a value

Ranges of Motion: Cervical Left Rotation – The User may enter a value

Ranges of Motion: Cervical Right Rotation – The User may enter a value

X-Ray Value Lateral: Cervical Curve – The User may enter a value

X-Ray Value Lateral: Forward Head Posture – The User may enter a value

X-Ray Value Lateral: C1 Angle – The User may enter a value

X-Ray Value AP: TxH – The User may enter a value

X-Ray Value AP: RzH – The User may enter a value

Neurologic Tests: Muscle C5 – The User may enter a value

Neurologic Tests: Muscle C6 – The User may enter a value

Neurologic Tests: Muscle C7 – The User may enter a value

Neurologic Tests: Muscle C8 – The User may enter a value

Neurologic Tests: Muscle T1 – The User may enter a value

Neurologic Tests: Reflexes C5 – The User may enter a value

Neurologic Tests: Reflexes C6 – The User may enter a value

Neurologic Tests: Reflexes C7 – The User may enter a value

Neurologic Tests: Reflexes C8 – The User may enter a value

Neurologic Tests: Dermatomes C2 – The User may select one test result
from system-provided list

Neurologic Tests: Dermatomes C3 – The User may select one test result
from system-provided list

Neurologic Tests: Dermatomes C4 – The User may select one test result
from system-provided list

Neurologic Tests: Dermatomes C5 – The User may select one test result
from system-provided list

Neurologic Tests: Dermatomes C6 – The User may select one test result from system-provided list

Neurologic Tests: Dermatomes C7 – The User may select one test result from system-provided list

Neurologic Tests: Dermatomes C8 – The User may select one test result from system-provided list

Neurologic Tests: Dermatomes T1 – The User may select one test result from system-provided list

Click Files – The system displays the Patient Files screen which contains the following:

Patient Name – The system displays the current Patient name

The system displays available document name, type and date modified for the current patient

Click Document information (by row) – The system displays User's description of document

Click New File – The system displays Windows Explorer to allow User to locate file to be added for current patient

Click Edit – The system displays the Document Description screen which allows User to enter or edit description for selected document

Click Delete – The system deletes the selected document from the patient record (document is not deleted from computer hard drive, only from its connection to the current patient in the software)

Click Hide – The system hides the Patient Files screen

Click Images – The system displays the Patient Images screen which contains the following:

Patient Name – The system displays the current Patient name

Image Thumbnails – The system displays thumbnails of all images currently associated with the current patient. User may click any thumbnail to display that image in the preview pane



The system displays available image name, and description for the current patient

Click New Image – The system displays Windows Explorer to allow User to locate image file to be added for current patient

Click Edit – The system displays the Image Description screen which allows User to enter or edit description for selected image

Click Delete – The system deletes the selected image from the patient record (image is not deleted from computer hard drive, only from its connection to the current patient in the software)

Image Preview Pane – The system displays the selected image

Double click image or thumbnail – The system opens the image in the computer's default image viewer

Click Hide – The system hides the Patient Files screen

Click Close – The system closes the Image screen



Click Other Exam Dates – The system displays a list of all other exam dates for the current patient. The User may click to display exam data for any available date

Click New Exam button – The system displays the New Exam screen

Click Save – The system saves changes

Click Cancel – The system closes the New Exam screen

Click Menu> Patient> New> Plan – The system displays the New Plan screen which contains:

Plan Date – The system displays system date in MM/DD/YYYY format.

Plan Notes Header – The system displays the current patient name and system date

Mechanical Settings: Height – The system displays the default height value

Mechanical Settings: Fulcrum – The system displays the default fulcrum value

Mechanical Settings: Traction – The system displays the default traction value

Click Plan Complete – The system designates the current plan as complete as of the system date

Session Information pane – The system displays Session Number, Unit Number, Session Total Time, Session Peak Fulcrum and Session Peak Traction for the 12 sessions comprising this Treatment Plan

Click Save – The system saves changes

Click Cancel – The system closes the New Plan screen

Click Edit – The system displays the Edit Treatment Plan screen which contains:

Description-Notes pane – The User may edit the description and add or edit notes related to this Plan



Click Plan Complete – The User may force system to mark this plan as complete

Click Individual Session Information Row – The system displays the Treatment Plan in Edit mode which allows the User to modify the following parameters for the current treatment and all future treatments in the plan

Height – The User selects a height value from the system-provided list

Fulcrum – The User selects a fulcrum value from the system-provided list

Traction – The User selects a traction value from the system-provided list

Time: Current – The User may modify the total session time for the selected session

Time: Increment – The User may modify the total session time incremental increase for each successive session in the plan

Time: Peak – The User may modify the peak session time for all successive sessions in the plan

Fulcrum: Current – The User may modify the fulcrum peak force for the selected session

Fulcrum: Increment – The User may modify the fulcrum force incremental increase for each successive session in the plan

Fulcrum: Peak – The User may modify the peak fulcrum force for all successive sessions in the plan

Traction: Current – The User may modify the traction peak force for the selected session

Traction: Increment – The User may modify the traction force incremental increase for each successive session in the plan

Traction: Peak – The User may modify the peak traction force for all successive sessions in the plan

Click Save – The system saves changes

Click Cancel – The system closes the Edit Plan screen

Click Extend – Click Extend - After the final treatment session of a plan is successfully completed, the EXTEND button will appear allowing User to extend the current treatment session plan

Extend Unavailable in TRIAL Mode - If User attempts to extend a plan while software is operating in Trial Mode, system displays an error screen: Cannot



Extend Treatment Plan "Cannot extend this treatment plan. If in trial mode, please purchase a valid license and enter key into the Registration form in the Tools menu."

No Active Plan - If User attempts to add a Patient who does not have an active plan to a Unit, the System displays an error screen: No Active Plan "There is not an active plan for (system inserts Patient name). Please create a new plan." "

Click PATIENT> EDIT – System displays Patient Record screen in Edit mode

Click PATIENT> DELETE – System displays Validate Delete Patient screen which contains:

Username – User enters valid Username

Password – User enters valid Password

Click Validate (Administrator and Doctor-level Users) – System confirms Patient Delete challenge screen which contains:

Click Yes – System deletes current patient

Click No – System closes challenge screen

Click Validate (Assistant-level Users) – System displays Validation Failed screen which informs Assistant-level User: "You are not authorized to perform this action."

Hover PATIENT> START SESSION IN – System displays clickable list of currently available units

Click Unit – System verifies that Ethernet communication exists between software and selected unit

If communication is verified, system adds next available Treatment Session for current patient to selected unit. System then displays that unit icon as having a pending treatment (full color with blinking border)

If communication is not verified, system displays Error Communicating with Unit screen



Click Unit Icon with Pending Treatment (blinking border) – System displays Patient Session screen which contains:

Patient Information Header pane – System displays Patient Name, Patient ID, Date of Birth, Provider, More Info clickable button

Unit Number – System displays Unit number

Session Elapsed & Total Time – System displays current session elapsed time and total time

System displays an Elapsed Time value which equals Total (Peak) Time minus current session running time

System displays a Total Time value which equals Peak Time value for current session from treatment plan

Traction Current & Peak Force – System displays current session traction force and peak traction force

System displays a Current Traction Force value being delivered by the system. The system calculates this force value by utilizing a piecewise linear function in which the system recalculates this force once each second.

System displays a Peak Traction Force value for the current session from treatment plan

Click Ease Up Control – System reduces (for the current treatment session) current traction force, peak traction force, current fulcrum force and peak fulcrum force each by 0.25 pounds, 1.11 Newtons or 0.11 kg depending on which Units of Measurement the User has selected. System creates a notation of those reductions of force actions in the session's comments.

Fulcrum Current & Peak Force – System displays current session fulcrum force and peak fulcrum force

System displays a Current Fulcrum Force value being delivered by the system. The system calculates this force value by utilizing a piecewise linear function in which the system recalculates this force once each second.

System displays a Peak Fulcrum Force value for the current session from treatment plan



Session Comments – User may add or modify comments related to this session

Session Count Down Timer – System displays active countdown timer showing session time remaining

Click Pause – System pauses current session

Click Stop – System stops current session and close Patient Session screen

Active Session Notification & Warning Screens

Error Communicating with Unit – System displays warning screen: "Connection was lost to iTrac Unit (system displays specific unit number). Please verify physical network connections. Attempt to reconnect?"

Plan Complete - When the final session of a treatment plan is completed, the system displays notification screen: Plan Complete "The plan is complete, you can either extend the current plan or re-examine the patient."

Cannot Start Session - If User attempts to drag or otherwise add a patient with a currently active or pending treatment on a Unit, the system displays error screen: Cannot Start Session "Patient in active session in another iTrac unit."

Error Communicating with Unit (No Connection Exists) - If an error exists in communicating with a Unit, system displays error screen: Error Communicating with Unit "There was an error communicating with the Unit (system displays unit number). Please ensure the unit's MAC address is correct and that all physical network connections are intact."

No Active Plan - If User attempts to drag or otherwise add a patient with NO active treatment plan onto a Unit, the system displays error screen: No Active Plan, "There is not an active plan for (system inserts current patient name). Please create a new plan."

Cannot Update Options - If User attempts to access Tools> Options while any session is active, the system displays an error screen: Cannot Update Options "Cannot edit options while a session is active. Please make sure all sessions are complete and try again."

Error Communicating with Unit (Lost Connection) - If communications with a Unit is lost during a session System displays an error screen: Error



Communicating with Unit (Lost Connection) "Connection was lost to Unit (system displays specific Unit number). Please verify physical network connections. Attempt to reconnect?"

Error Communicating with Unit (Failed Reconnect Attempt) - If an attempt to reconnect (see above) fails, System displays an error screen: Error Communicating with Unit (Failed Reconnect Attempt) "Connection to Unit (system displays specific Unit number) not restored. Please verify physical network connections. Attempt to reconnect?"

Active Sessions on Exit - If User attempts to close software application while one or more treatment sessions are active, system displays warning message: Active Sessions on Exit "There is at least one session controller still active. All active sessions will be stopped."

No Active Patient - If User attempts to right click a Unit icon to add Active Patient to that unit, system displays error screen: No Active Patient "There is no active patient available. Please open the patient's file from the search list and try again."


Unit Icons Session Progress - System represents progress of a treatment session on a specific unit by means of a colorized progress bar, beginning at the left with green, transitioning toward the right and transforming the color of the bar through orange and finally red as the end of the treatment session nears. The system represents any unit currently in Pause mode as flashing yellow.


Unit Icons NOT open in Active Session Window - The system displays the Session Time Remaining directly on the Unit icon for every Unit NOT currently open in the Active Session Window.

Click Menu> Help – The system displays the Help screen which provides User access to a Windows-based Help tool

Click Menu> About – The system displays the Information Screen

Technical Specifications:

T9000	115V version	
Rated Voltage	115 VAC	
Rated Frequency	60 Hz	
Current	10 Amps	
Fuse Type	T10 Amp AGC (time delay)	
Maximum Load Capacity	350 lbs	
Duty cycle	Continuous	
Electrical Classification	Class I	
Electrical Type	 Type B	
IP Rating	IPx0	
Equipment is not suitable for use in the presence of flammable mixtures		

T9010	230V version	
Rated Voltage	230 VAC	
Rated Frequency	50 Hz	
Current	10 Amps	
Fuse Type	T10 Amp AGC (time delay)	
Maximum Load Capacity	350 lbs	
Duty cycle	Continuous	
Electrical Classification	Class I	
Electrical Type	 Type B	
IP Rating	IPx0	
Equipment is not suitable for use in the presence of flammable mixtures		

Safety Approvals and Recognition:

Standard for Safety for Medical Electrical Equipment; Part 1: General Requirements for Safety
UL 60601-1, 1st Edition: 2003, Rev: 2006/04/26

Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety;
CAN/CSA-C22.2 No. 601.1-M90, Issue: 1990/01/01 Rev: 2003/11

CENELEC EN60601-1 Issue: 1990/08/01 Med. Elec. Equip. Part 1: Gen. Req. for Safety Incorporates
Corrigendum July 1994; Includes Amd. A1: 1993, A11:1993, A12, A2: 1995 and A13: 1996; IEC 601-1:
1988 + A1: 1991 + A2: 1995 + Corrig 1995

IEC 60601-1-2:2007
Class B Radiated and Conducted Emissions
Immunity for Non-Life-Supporting Equipment



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Guidance and manufacturer's declaration – electromagnetic emissions			
The iTrac is intended for use in the electromagnetic environment specified below. The customer or the user of the iTrac should assure that it is used in such an environment			
Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The iTrac uses RF energy only for its internal function. therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
Conducted emissions CISPR 11	Class B	The iTrac is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes	
Harmonic emissions IEC 61000-3-2	Class A per Ed. 3.2 (2009) (European limits)		
Voltage fluctuations/ Complies flicker emissions IEC 61000-3-3	Complies		
Guidance and manufacturer's declaration – electromagnetic immunity			
The iTrac is intended for use in the electromagnetic environment specified below. The customer or the user of the iTrac should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iTrac requires continued operation during power mains interruptions, it is recommended that the iTrac be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m 50Hz / 60Hz	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT IS THE A.C. MAINS VOLTAGE PRIOR TO APPLICATION OF THE TEST LEVEL.			
Guidance and manufacturer's declaration – electromagnetic immunity			
The iTrac is intended for use in the electromagnetic environment specified below. The customer or the user of the iTrac should assure that it is used in such an environment.			

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the iTrac, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.17 \times P$ 150 kHz to 80 MHz</p> <p>$d = 1.17 \times P$ 80 MHz to 800 MHz</p> <p>$d = 2.33 \times P$ 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people</p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iTrac is used exceeds the applicable RF compliance level above, the iTrac should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iTrac.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the iTrac

The iTrac is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iTrac can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iTrac as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.33 \sqrt{P}$
0,01	.117	.117	.233
0,1	.37	.37	.737
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



Care & Maintenance

These devices will give many years of trouble free service. Frequently check to make sure all hardware (nuts, bolts, etc.) are securely fastened. Should any problems occur with this unit, contact your authorized Pivotal Health Solutions, Inc. iTrac Dealer or call Pivotal Health Solutions, Inc.

Remove all power to iTrac prior to cleaning or performing maintenance.

The air compressor requires periodic maintenance. Please see Compressor User Manual for compressor care instructions. A table indicating periodic maintenance schedule, and instructions is included in this manual.

If the device is located in an area where it is subjected to extreme amounts of moisture or humidity, the moving joints on the frame and wheel casters should be lubricated occasionally with light machine oil.

Between patients, all surfaces should be cleaned using standard cleaning technique, paying particular attention to the components that come in contact with the body. The iTrac vinyl upholstery surface and fulcrum cushion may be cleaned with a mild detergent or soap and water. For the seating surfaces, apply the solution to a large area and allow it to soak for a few minutes. Brisk rubbing with a cloth should remove most dirt. Repeat the procedure in the case of stubborn or embedded dirt. Rinse with clean water. A soft-bristle brush may also be used.

The headgear should machine washed and hung to air dry. Head harnesses should be washed between uses, or assigned exclusively to an individual patient.

Upholstery Notice

OUR UPHOLSTERY ONLY CARRIES A 90 DAY WARRANTY FROM DATE OF PURCHASE.

UPHOLSTERY ON THE iTrac OFTEN WILL NOT WEAR AS LONG AS NON MOVING TABLES. THE CONSTANT MOVEMENT OR MOTION OF THE DEVICE AND THE PATIENT ON THE DEVICE AND UPHOLSTERY CAUSES INCREASED WEAR AND UPHOLSTERY BREAKDOWN AT A RATE OF NEARLY FOUR TO FIVE TIMES THAT OF A NORMAL NON MOVING DEVICE. THIS IS THE REASON UPHOLSTERY WEARS FASTER AND NEEDS TO BE REPLACED SOONER.

THIS IS NOT A FLAW IN THE UPHOLSTERY, BUT JUST THE NORMAL INCREASED WEAR CAUSED BY MOTION AND NORMAL USE. ALWAYS FOLLOW CLEANING INSTRUCTIONS SUPPLIED WITH YOUR NEW PIVOTAL HEALTH DEVICE.

Upholstery Care and Cleaning Guide

- For light soiling, a solution of 10% household liquid dish soap with warm water, applied with soft damp cloth. Rinse with clean water and dry.
- For heavy soiling, dampen a soft white cloth in a one to one (1:1) solution of Fantastik® and water OR Formula 409® and water. Rub gently and rinse with a water dampened cloth.
- For more difficult stains, dampen a soft white cloth with a solution of household bleach (10% bleach / 90% water). Rub gently and rinse with a water dampened cloth to remove bleach concentration.
- DO NOT USE ALCOHOL BASED CLEANING AGENTS! IMPROPER CLEANING WILL CANCEL THE WARRANTY.

This information is not a guarantee and does not relieve the user from the responsibility of the proper and safe use of the product and all cleaning agents. The use of certain agents can be harmful to the surface appearance and lifespan of vinyl. Pivotal Health Solutions assumes no responsibility resulting from the use of such agents to the vinyl.

Cervical Capture Cleaning Guide

- For light soiling, a solution of 10% liquid laundry detergent with warm water, applied with soft damp cloth. Rinse with clean water and dry.
- For heavy soiling remove the cervical capture and machine wash using laundry detergent and air dry.

Troubleshooting

For repairs call Pivotal Health Solutions for a Qualified Service Technician.

If the main power indicator lamp is not glowing, make sure the unit is receiving power:

- Check the plug to make sure it is securely plugged into a specified electrical wall outlet.
- Check the plug to make sure it is securely plugged into the receptacle at the front of the Power Control Box.
- If the device is plugged in, check building circuit breaker to make sure wall outlet is receiving electricity.
- The 10 amp mains fuses may have blown. **ONLY QUALIFIED SERVICE PERSONNEL** should replace as follows:
 - Remove the Power Cord from the wall outlet.
 - Remove the Power Cord from the power input socket.
 - Using a small flat screwdriver, gently slide out the fuse holder. The cover will drop down.
 - Remove the blown fuse from the fuse holder and replace with a new fuse.
Note: See page Care and Maintenance section for fuse rating. If both fuses are blown, replace them both.
 - Gently push fuse holder back into place on the front of the power input socket. The holder will snap into place.

If the traction unit doesn't work:

- Make sure the unit is getting power.
- Make sure the Patient Control Switch is not physically damaged or something is not pressed against the button.
- If the compressor is running but there is no traction force, check for air leaks between the pump and cylinders (determined by hissing sound during operation).
- If the software will not communicate or control the device, **STOP** and call service. Do NOT attempt to use the unit until the problem is resolved.

Environmental Conditions:



- This unit should be operated, transported and stored in temperatures between 40° F (4.4° C) and 100° F (37.8° C), with relative humidity ranging from 30% - 80%.

If you have further questions, please call your authorized Pivotal Health Solutions, Inc. iTrac Dealer, or call Pivotal Health Solutions, Inc., Customer Service.



Replacement Parts & Accessories

Below is a listing of replacement parts and accessories for the Pivotal Health Solutions, Inc. iTrac. Please call your authorized Pivotal Health Solutions, Inc. iTrac Dealer, or call Pivotal Health Solutions, Inc. Customer Service for details and pricing.

Item	Description
T1000	Telescoping-Column Electromechanical Actuator
T1001	Digital / Analog I/O
T1002	LED 24V; LEADS; GREEN; PANEL.
T1003	Compressor
T1004	Solenoid Valve
T1005	Low Flow regulator
T1010	iTrac Start / Pause PB
T1011	Pressure Gauge
T1012	Elevation Button
T1013	Blue Neon Lamp
T1015	Chin Harness
T1016	Fulcrum Harness
T1017	Fulcrum Cylinder
T1018	Traction Cylinder
T1019	Traction Cord Retractor
T1020	Traction Cord Guide Eyelet
E7058	Patient Stop Switch
E7053	24v Power supply

Warranty and Repair

Contact Customer Service at 1-800-743-7738.