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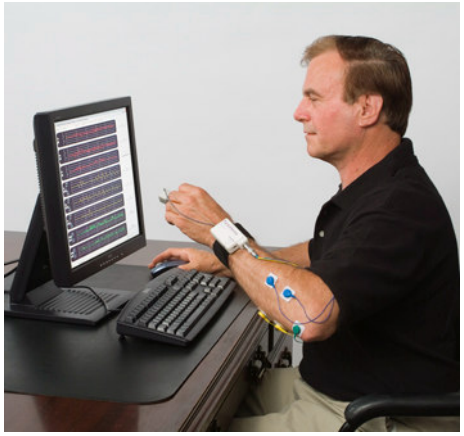
ParkinSense™

QUANTITATIVE MOTOR ASSESSMENT SYSTEM



User's Guide

Preliminary Release 01-20-06

CleveMed

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TABLE OF CONTENTS

Introduction **4**
Intended Use *4*
Contraindications *4*
Warnings *4*
Package Contents and Warranty Information *6*
Chapter 1: About ParkinSense **7**
General Device Description *7*
User Unit *8*
Sensors *9*
User Interface Software *10*
Chapter 2: Setting Up ParkinSense **11**
Installing the ParkinSense Program *11*
Charging ParkinSense User Unit *11*
Installing the ParkinSense Hardware *11*
Starting the ParkinSense Program *15*
Obtaining USB data communication port: *15*
Chapter 3: About ParkinSense Software **17**
Running the Application *17*
Using the Application *17*
Accessing the Patient Database *18*
Adding a Patient *18*
Updating a Patient *19*
System Setup *19*
Collecting Data Wirelessly Using Bluetooth *22*
Starting Data Acquisition *23*
Acquired Data Display *23*
Saving Acquired Data *23*
Stopping Data Acquisition *23*

Clevemed Proprietary Information

Collecting Data From Memory *24*
Switching Data Modes *25*
Erasing Memory *25*
Reviewing Saved Data *26*
Printing Current Graph *28*
Graph Color and Scale Setup *29*

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Introduction

Intended Use

ParkinSense is not FDA cleared to market. It is not intended for use in experimentation that involves human testing without specific IRB approval.

The ParkinSense movement disorders quantification system is intended for use by researchers analyzing quantitative features of movement disorders which require recording motion and/or electrical activity of muscle.

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS: (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE, AND (2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRED OPERATION.

NOTE: THE MANUFACTURERE IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERVERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE PATIENT'S AUTHORITY TO OPERATE THE EQUIPMENT.

Contraindications

Interference may occur in the vicinity of equipment marked with the following symbol:

This device complies with CFR 47 – Part 15, 15.109(b) and 15.247.

Warnings

!!!! Do NOT connect the system to a computer via the mini-USB port at the same time a subject is connected to the electromyography electrode leads.

!!!! Do NOT expose the system to water. Water exposure may permanently damage the unit.

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Minimum System Requirements

Personal computer with Pentium III™ 500 MHz or higher processor (or equivalent);
Microsoft® Windows 98/NT 4/2000/XP;
256 MB of installed memory;
Minimum 500 MB free hard disk space (1 GB recommended);
CD-ROM Drive;
1024x768 or greater display resolution;
Mouse or other pointing device;
One USB port
Bluetooth™ Radio (Included with ParkinSense kit, however other Bluetooth adapters may be used)

The ParkinSense system communicates with your computer using a Bluetooth Radio link. There is a Bluetooth radio embedded inside the ParkinSense unit which will communicate with a Bluetooth radio connected to your computer. A USB Bluetooth adapter is provided with the ParkinSense system, however other Bluetooth adapters may be used.

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Package Contents and Warranty Information

Cleveland Medical Devices Inc. thanks you for your recent product purchase. CleveMed offers phone technical support (9 AM-5 PM EST) and warrants the ParkinSense (parts and labor) for 90 days from the date of purchase. Technical support after the 90 day period will be charged hourly. Call CleveMed for hourly rates. For your benefit, we recommend that you record the pertinent details below. If necessary, this information will allow us to better serve your needs. We highly recommend that you staple a copy of the sales receipt to the blank pages in the back of this manual.

Please check to make sure your kit has the required components and records the requested data.

Data of Purchase:_____

S/N:_____

(1) ParkinSense Unit
(1) Data Cable, USB
(1) USB Bluetooth Adapter
(1) EMG snap lead cable
(1) Flexible wrist band
(1) ParkinSense software
(1) User's Guide; this document

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Chapter 1: About ParkinSense

General Device Description

The ParkinSense movement disorder assessment system can be utilized for a wide variety of applications to quantify motion and electrical muscle activity. The system includes a user worn unit, a radio for wireless data transmission, and software to collect, manage, and analyze data. The ParkinSense user unit is typically worn on the wrist and finger of a subject (Figure 1). The wrist module slips over a comfortable band worn around the wrist or forearm. A sensor module then slips over the middle finger of a subject. ParkinSense provides a total of eight channels of data including three channels of accelerometry, three channels of gyroscopes, and two channels of electromyography (EMG). The system measures three dimensional motion using three orthogonal accelerometers and three orthogonal gyroscopes located in the sensor module. The system also measures two channels of EMG. The lemo connector input on the wrist module provides connection for the two channel EMG snap leads which come with the system.

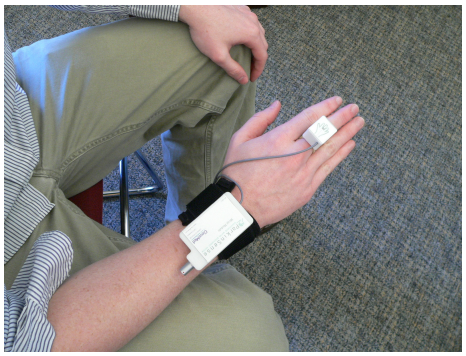

Figure 1. The user unit is worn by the subject and consists of finger and wrist worn components.

Table 1. ParkinSense system specifications.

Sensor Module Size	0.57 x 0.80 x 1.03 in.
Sensor Module Weight	0.7 oz. / 20 g.
Command Module Size	2.88 x 1.56 x 0.66 in.
Command Module Weight	3.25 oz. / 92 g.
Electromyography	Lemo Connector with 5 leads (2 differential EMG leads and one ground)
Wireless Link	Bluetooth™ Radio
Data Transmission Range	~ 20 feet (line of sight)
Data Rate	57.6 kbps, 4800 bytes/s throughput
Transmission Frequency	2.400-2.483 GHz
Transmission Bandwidth	1 MHz
Batteries	Rechargeable Lithium Polymer 850 mA-Hr
Battery Life	12 Hrs

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User Unit

The user unit (Figure 1) is worn by the subject and consists of two parts connected by a thin, flexible grey cable. To put the user unit on, the subject should first slip the thin, flexible wrist band over their forearm just below their wrist. Next, the sensor module of the ParkinSense User Unit should be place over their middle finger with the grey cable facing toward the wrist. The clip of the wrist module should then be slid over the wrist band.

Figures 2 – 5. From left to right. 2Add pictures here to show setup. Fig 2. Wrist band alone, Fig 3. Sliding over the finger, Fig 4. Sliding over wrist band. Fig 5. Complete System.

The ParkinSense user unit integrates the following features:

Bluetooth Radio – A Bluetooth Radio is integrated in the ParkinSense system. This provides real-time data transmission up to a computer with another Bluetooth radio. The transmission range is 30 feet line of sight.

On Board Memory – In addition to data transmission over the wireless link, data is continually stored to on board flash memory whenever the system is turned on. The system can store up to 12 hours of data.

Mini USB Connector – The mini USB connector provides a method to directly connect to a computer with the ParkinSense software installed. This provides three important functions:

- Data download from the user unit memory
- Erasing the user unit memory
- Recharging the user unit battery

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Figure 6. The ParkinSense wrist module includes both a mini USB and lemo connector.

Electromyography – The user unit provides a lemo connector input for two channels of electromyography (EMG). The electromyography data transmitted over the wireless link and saved in memory is processed data. The user unit samples EMG at 2 KHz. However, the root mean square (RMS) value of the EMG signal is processed every 7.8 milliseconds and stored to memory or sent over the wireless link. This provides data synchronization between the EMG and the mechanical sensors which are sampled at 128Hz (or every 7.8 milliseconds). (Table 2)

Gyroscopes – The finger worn sensor module includes three orthogonally positioned gyroscopes. This provides three axes of angular rotation data. (Table 2)

Accelerometers - The finger worn sensor module includes three orthogonally positioned accelerometers. This provides three axes of linear acceleration data. (Table 2)

Sensors

ParkinSense integrates motion sensing and EMG in a single device. Eight channels of data are providing including three orthogonal accelerometers, three orthogonal gyroscopes, and two channels of differential EMG. The exact sensors specifications are shown below (Table 3).

Table 3. ParkinSense system sensor specifications.

	Angular Rate	**Acceleration**	**Electromyography**
Sensor Type	MEMS Gyroscopes	MEMS Accelerometers	Snap electrodes
Number of Channels	3 Orthogonal Channels	3 Orthogonal Channels	2 differential channels
Input Range	±1200 deg/sec	±5 g	±5 mV
Min. Freq (3dB)	0Hz	0 Hz	30 Hz
Max. Freq (3dB)	15 Hz	15 Hz	1024 Hz
Input Noise	<1.6 deg/sec RMS	<2 mg RMS	<15 µV p-p
CMRR	N/A	N/A	>60 dB
A/D resolution	12-bit	12-bit	12-bit
Sampling Rates	128 sps	128 sps	2048 sps per channel
DC offset rejection	N/A	N/A	300 mV
Input Impedance	N/A	N/A	>20 Mohm

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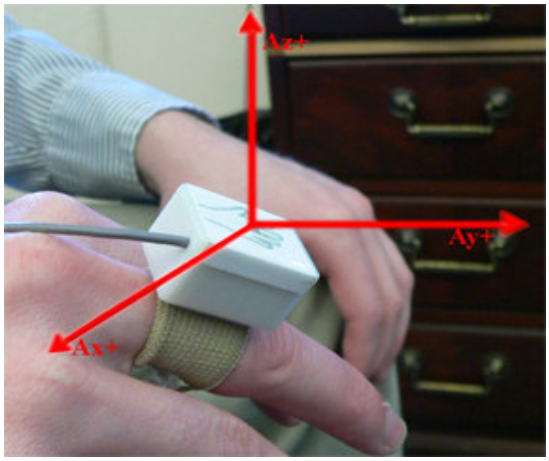

Accelerometer - axis

Add a picture here to show the orientation of the sensors. (Fig 7)

User Interface Software

ParkinSense user interface software provides several functions including:

- Real-time data display
- Saving real-time data to file
- Patient database and file management
- Saved data review
- Downloading data from the user unit
- Erasing the memory of the user unit
- Frequency analysis of saved data files

The software is explained in greater detail in Chapter 3.

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Chapter 2: Setting Up ParkinSense

Installing the ParkinSense Program

1. Insert the ParkinSense installation CD-ROM into your computer's CD-ROM drive.
2. Double-click on the ParkinSense Installer program.
3. Follow the on-screen prompts to install the software.
4. Once the software has been installed, start the ParkinSense software.

Charging ParkinSense User Unit

1. Locate the ParkinSense User Unit.
2. Plug the large end of the USB data cable into your computer's USB port. Plug the small end of the USB cable into the ParkinSense User Unit.
3. The green LED should come on, indicating the device is charging.

Installing the ParkinSense Hardware

1. Make sure the device is fully charged before first use.
2. Turn on the ParkinSense User Unit. A series of beeps indicates that the device is on and ready for wireless data transmission.
3. Plug the Bluetooth Device into an open USB port.
4. Go to your Bluetooth Devices Manager by going to

Start Menu → Control Panel → Bluetooth Devices

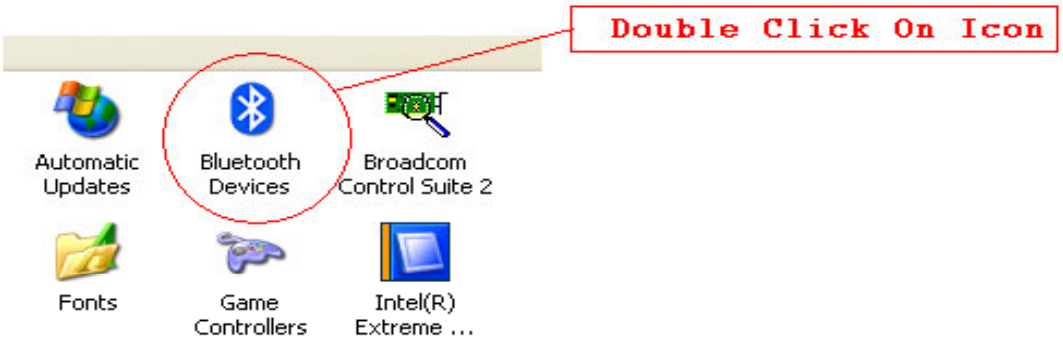

Figure 1. Control Panel to Bluetooth Devices Manager

5. From the Bluetooth Devices Manager you can add the ParkinSense User Unit. Click on **ADD** as shown in **Figure 2.**

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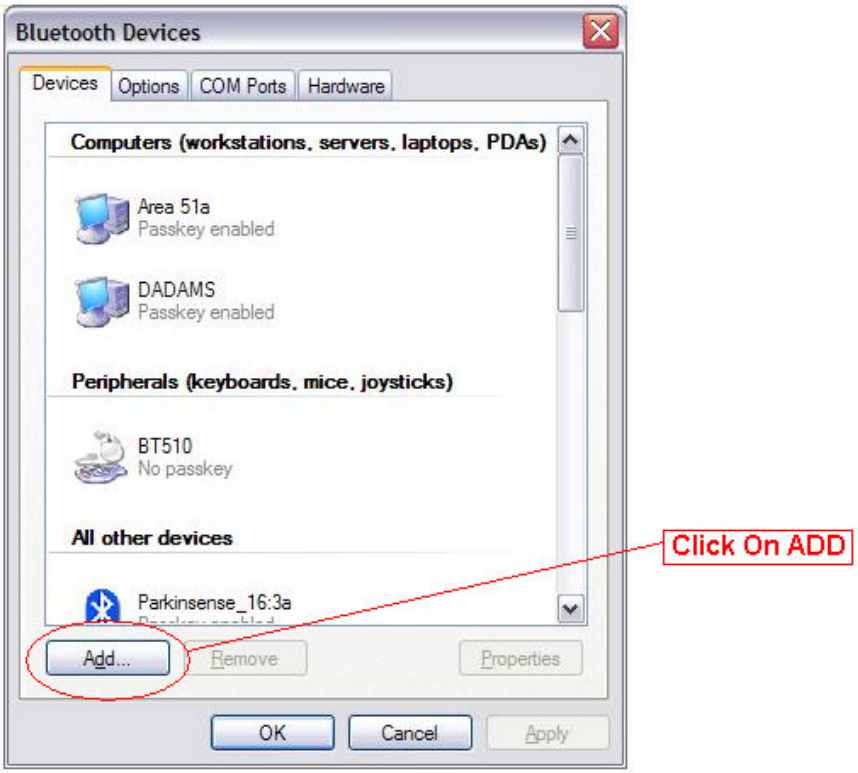

Figure 2. Bluetooth Devices Manager

6. A Bluetooth Device Wizard should pop up that will guide you through the process of adding your ParkinSense User Unit. Check the box that says:
   ☑ My device is set up and ready to be found. , and then hit **Next>.**

7. The Bluetooth Device Manager will search for your device. After the search has been completed, look for your new device on the list of Bluetooth devices. Consult **Figure 3.** Click on the new device, and then hit **Next>**.

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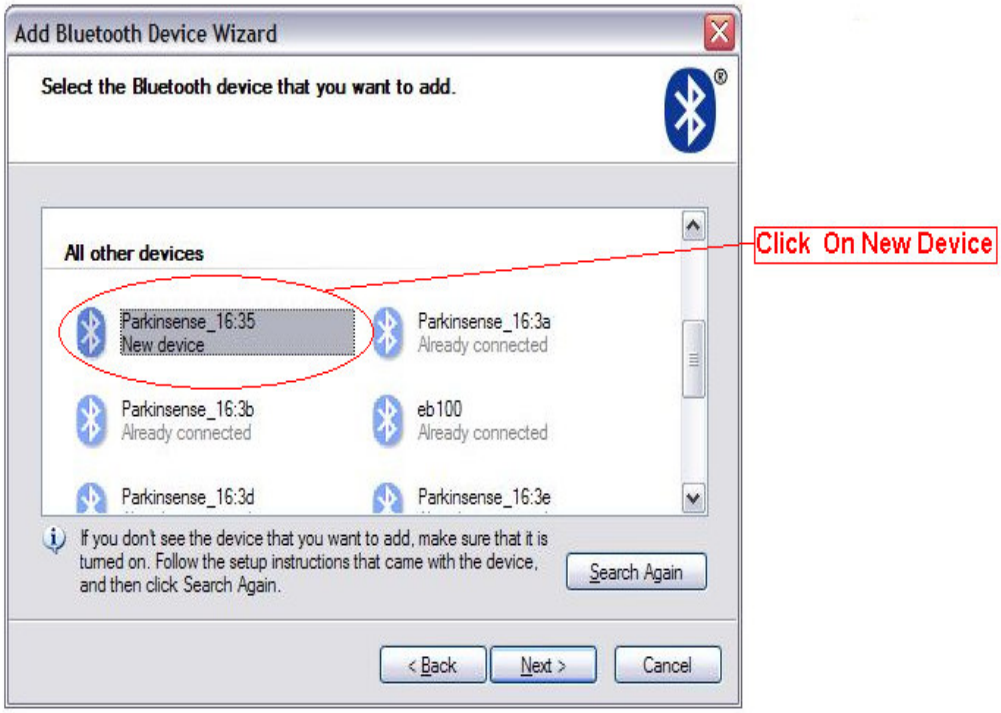

Figure 3. Add Bluetooth Device Wizard

8. The wizard will now prompt you for a passkey for the device. Select "Use the passkey found in the documentation" and enter four zero (**0000**) as shown in **Figure 4,** and then hit **Next>**. The wizard will now install the ParkinSense User Unit. After it is installed, hit **Next>**.

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Figure 4. Step 8

9. After the device is installed, the wizard will display the new port assigned to your device. The new port for your device is label as "Outgoing Com port:" as shown in **Figure 5.**

Figure 5. Step 9

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Note : When using an external Bluetooth device, attaching the USB Bluetooth device to a different USB port will change the radio port of your ParkinSense User Unit.

Starting the ***ParkinSense*** *Program*

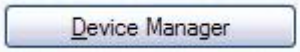
1. Click the **Start** Button
2. Point to **Programs**
3. Click on **ParkinSense**

Obtaining USB data communication port:

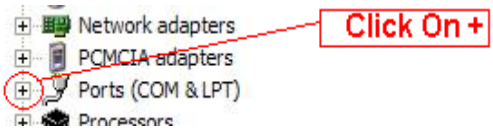
1. Plug the large end of the USB data cable into your computer's USB port. Plug the small end of the USB cable into the ParkinSense User Unit.
2. Turn on ParkinSense User Unit.
3. From the Start menu, go to settings then to Control Panel.
   Start → Control Panel
4. Click on icon label as "System," shown to the right.
   This will bring you to System Properties.

5. From System Properties, go to Hardware by clicking on

6. Go to the Device Manager by clicking on under the Hardware Tab



7. In device manager, click on **"+"** beside "Ports (Com & LPT) to expand the menu tree.



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8. Locate the line that is labeled “USB Serial Port (COMX)” under the Ports menu tree. This is the port that you will use for USB data transmission. An example of what you might see is shown below.

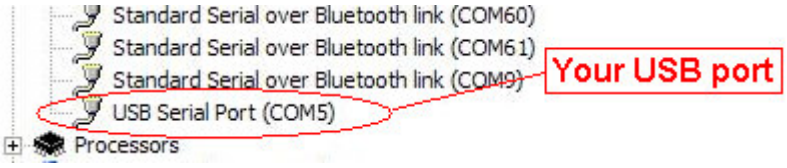

Figure 6. Menu Tree under Ports.
In this case, the USB port is **COM5**

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Chapter 3: About ParkinSense Software

Running the Application

When the **ParkinSense Data Collection Package** has been installed, it can be run from the Windows Start menu.
Click Start → Programs → ParkinSense

Using the Application

Once the program is running, a main menu will appear.

Figure 7. The ParkinSense Main Menu

From this menu, the patient database can be accessed, new data can be collected, and old data can be reviewed.

To exit the program, click the Exit button.

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Accessing the Patient Database

To access the patient database, click on the Patient Database button. The following menu is displayed. The Patient Database stores all patients' personal information, as well as their data results.

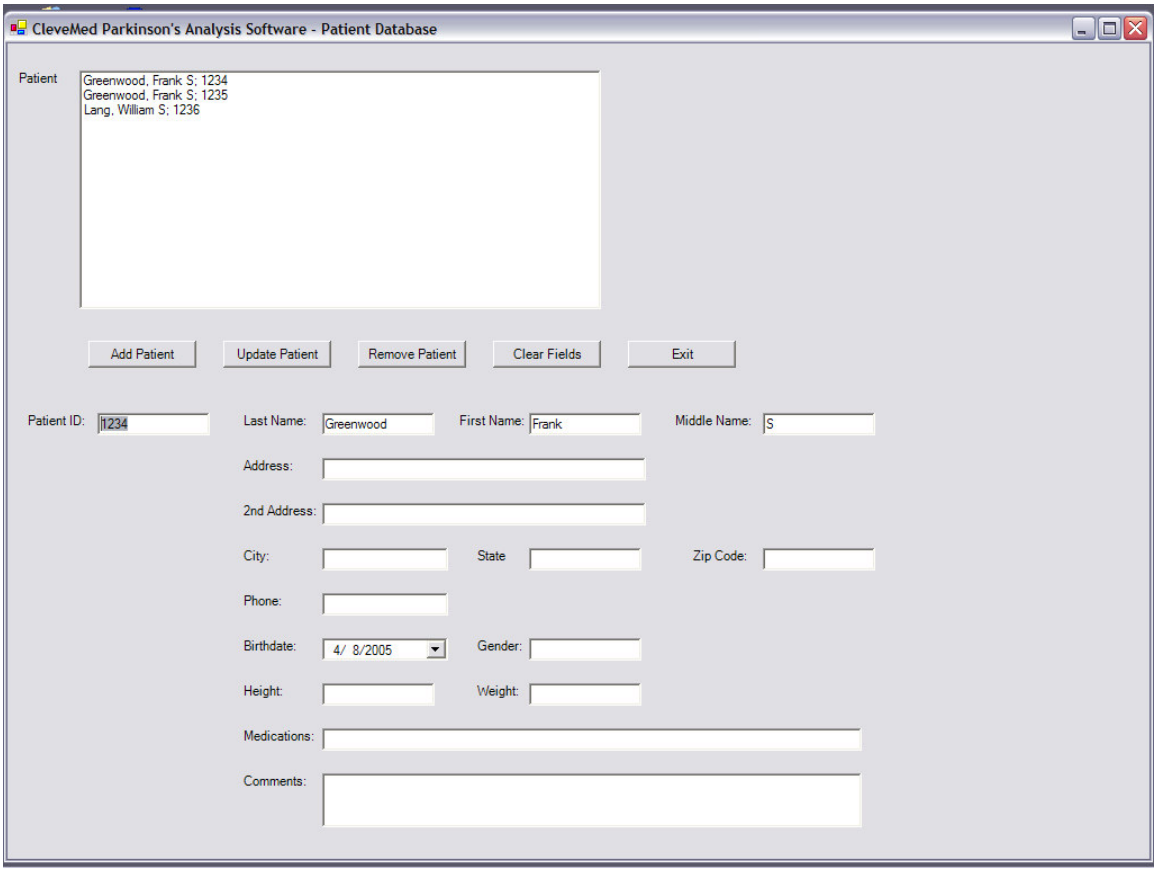
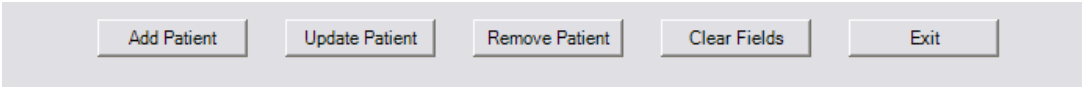


Figure 8. Patient Database

In the patient database, the user can:

- Add a patient
- Update a patient's information
- Remove a patient from the database



Adding a Patient

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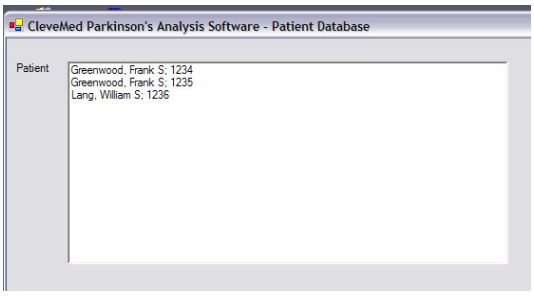
To add a patient, fill in the necessary information into the text boxes. Once complete, click on the Add Patient button to submit the information.

Updating a Patient



To change a patient's information in the database, click on the patient's name on the database list.

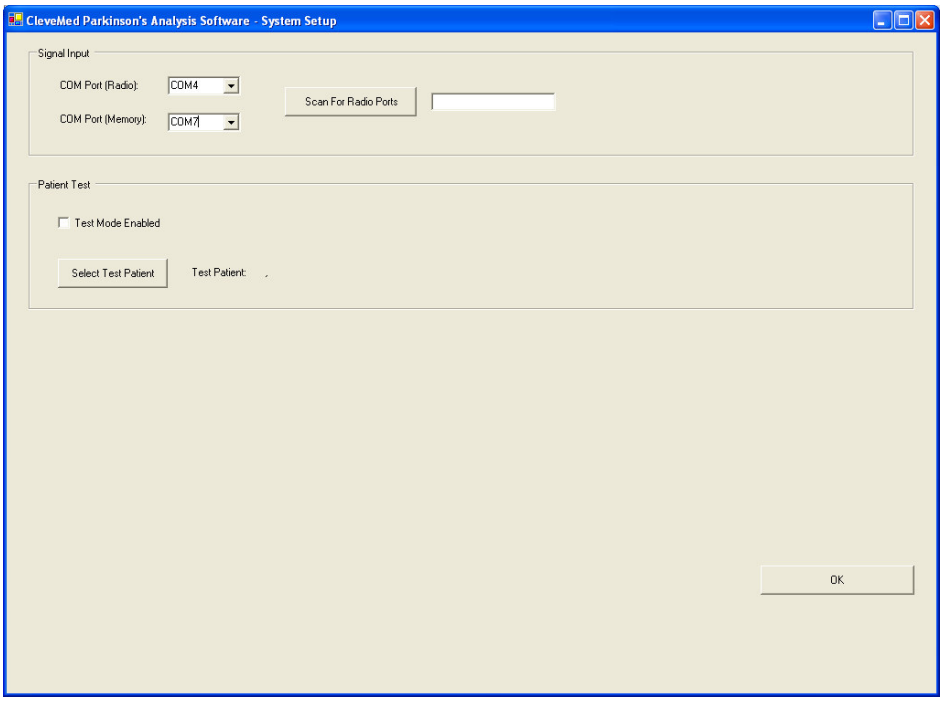
Change the necessary data, and then click Update Patient.

Removing a Patient

Highlight a patient's name on the Patient List. Then click Remove Patient. This will remove all the patient's information in the database, as well as the patient's recorded data.

To exit the Patient Database, click Exit.

System Setup



From the main screen click on the System Setup button to access the System Setup menu.

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The System Setup menu allow you to set up the proper ports for wireless and USB data acquisition between the ParkinSense user unit and the software package.

- **COM Port (Radio):** This is the port required for wireless data acquisition via Bluetooth. Enter the port obtained during the ParkinSense User Unit setup here. It can also be detected automatically by doing a Scan.
- **COM Port (Memory):** This is the port required for downloading data from the ParkinSense User Unit memory. Fill in the port obtained from the "Obtaining USB data communication port" section.

Scan For Radio Ports

This function allows you to scan for COM Port (Radio) of a ParkinSense User Unit. Follow the following step to obtain a Radio port by scanning:

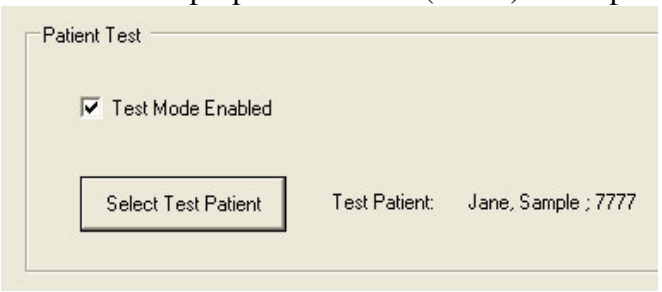
1. Make sure ParkinSense user unit is on and unplugged from the USB data cable.
2. Click on the "Scan For Ports" button and the status indicator should change from blank to Scanning…
3. When the status indicator displays "Done!," use the pull down menu of the COM Port (Radio) to select the Radio port. When one has more than one ParkinSense User Unit on, the scan will return the ports of all the devices turned on during the scan.

To exit System Setup and save the changes that you have made, click on OK.

Patient Test Mode

System Setup allowed you to change the mode of operation of the software, from regular data acquisition to Patient Test operation. In Patient Test mode, the software will guide the patient through a series of activities and record those data to the patient's profiles. To switch to Patient Test mode, follow these steps:

1. Make sure the proper COM Port (Radio) is setup for wireless data acquisition.



2. Under Patient Test, check the box right next to "Test Mode Enabled".
3. Click on "Select Test Patient" to select a patient for which the test is perform on from the drop down menu. After you have selected a patient, click "Load Patient" button to continue.

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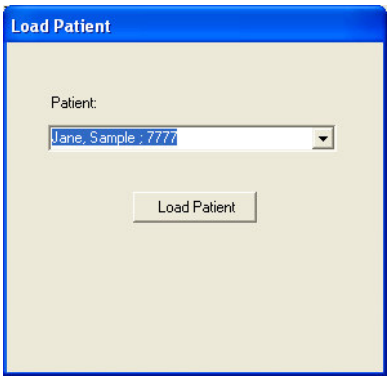

4. At the main screen of System Setup, click OK to save the changes you have made.
5. You will now return to the main screen of the ParkinSense Software, hit the space bar to begin the Patient Test. On screen direction will guide you through a set of activities, while recording the result acquired from these activities in the patient ID folder.

6. To exit out of Patient Test operation mode, simply go back into System Setup and uncheck the checkbox label as “Test Mode Enabled”.

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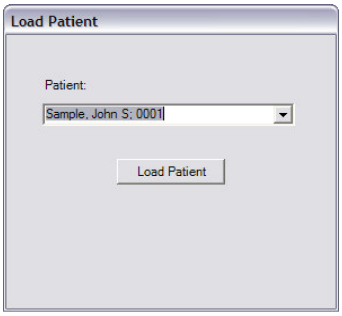
Collecting Data

Collecting Data Wirelessly Using Bluetooth

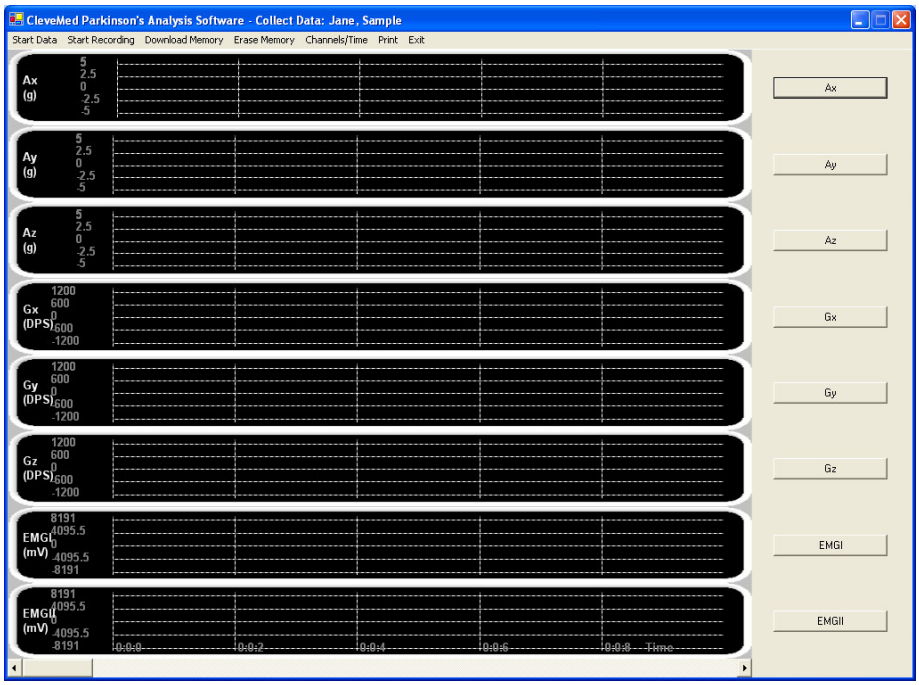
Make sure that you have set up the proper **port setting** in System Setup before you start collecting data.

Click on the "Collect Data" button to open the data collection mode.



A window will pop up to Load a Patient. Use the pull down menu to choose the correct patient, then click Load Patient.

Once the patient is loaded, the data screen appears.



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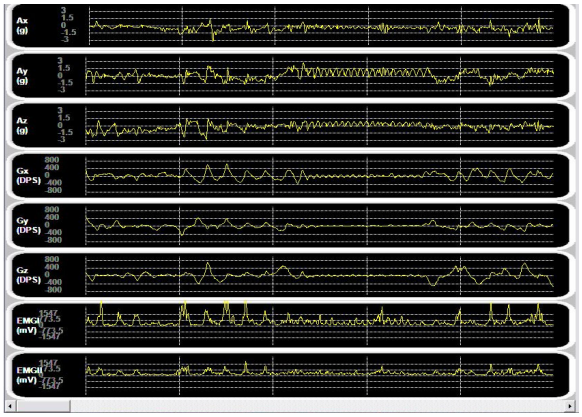
Starting Data Acquisition

To begin data acquisition, ensure the ParkinSense arm device is switched to *ON*, and click **Start Data** on the tool bar.

When communication with the ParkinSense arm device is established, data will begin scrolling across the graph display.

Acquired Data Display

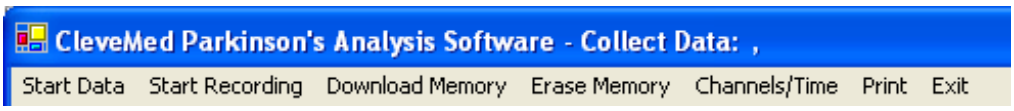


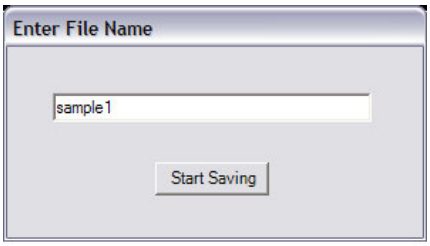
The graph area of the "Collect Data" window in ParkinSense Research ToolBox displays real-time data as it is acquired by the User Unit and transmitted to the PC.

By default, there are eight channels visible scaled at 10 seconds.

To change the axis scales and number of visible channels, click **Channels/Time** on the tool bar. Check the channels you would like to be visible, and uncheck those channels that you would like to hide. Chose the time scale most suitable for your application and click **OK** to save.

Saving Acquired Data





To begin saving the received data, click the Start Recording button at any time. This will bring up a window called Enter File Name. Enter a pertinent file name to save the patient's data for this trial. After entering a file name, click Start Saving. This will begin the recording process.

Stopping Data Acquisition

Click the **Stop Data** button on the tool bar to end data acquisition. If data is recording, click **Stop Recording** to end recording.

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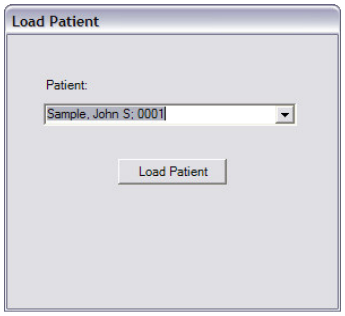
Collecting Data From Memory

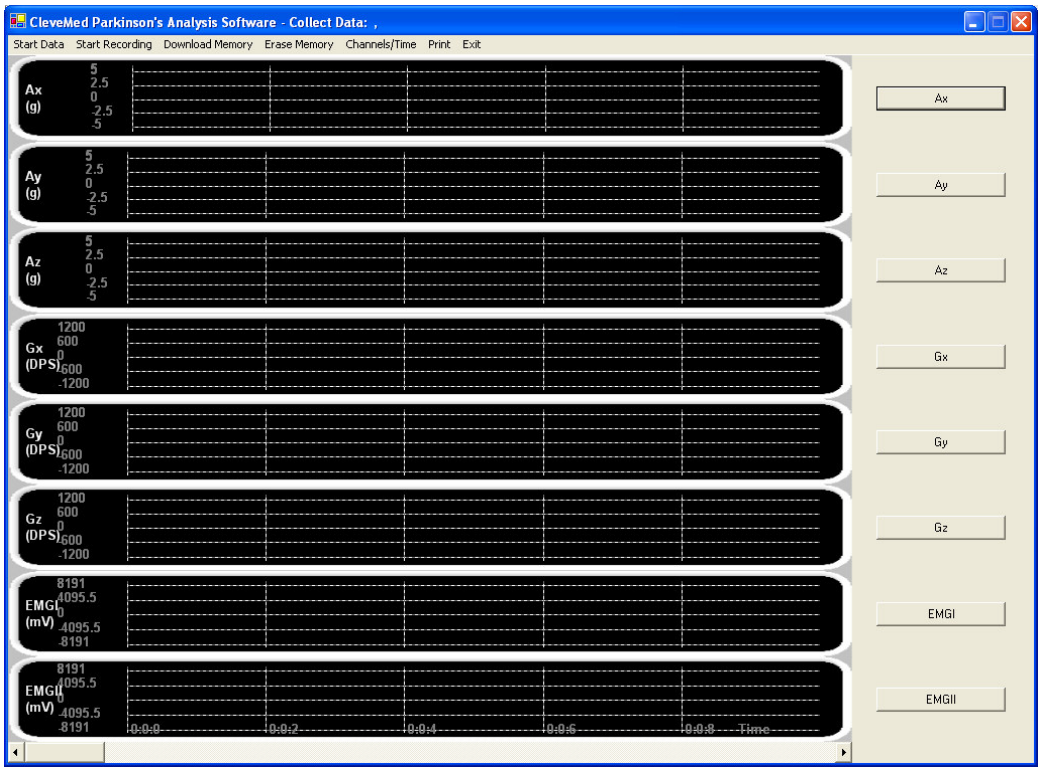
When the ParkinSense User Unit is on, the device immediately starts recording data to its internal memory. To download data from this memory at anytime, go through the following steps.

1. From the main screen, click on the Collect Data button to open the data collection mode.



2. A window will pop up to Load a Patient. Use the pull down menu to choose the correct patient and click Load Patient.

3. Once the patient is loaded, a data screen appears.



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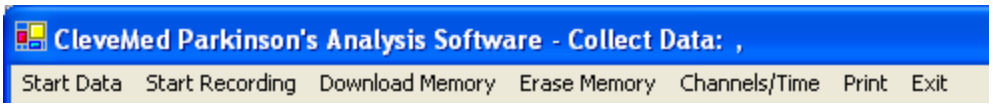
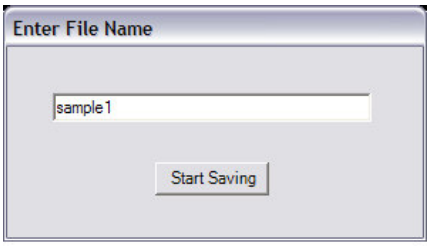
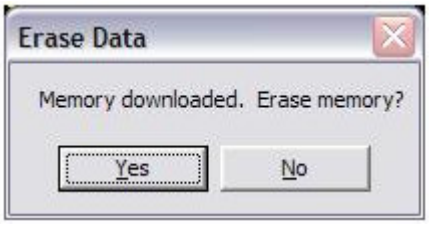
Make sure that you have setup the proper port setting in System Setup before you start downloading data from memory. Begin by turning on your ParkinSense User Unit. While the ParkinSense User Unit is on, plug the large end of the USB data cable into your computer's USB port. Plug the small end of the USB cable into the User Unit.





Click the **Download Memory** button to start downloading the data from memory into your desktop. This will bring up a window called Enter File Name. Enter in a pertinent file name to save the patient's data for this trial. After entering a file name, click Start Saving. This will begin the transferring process.



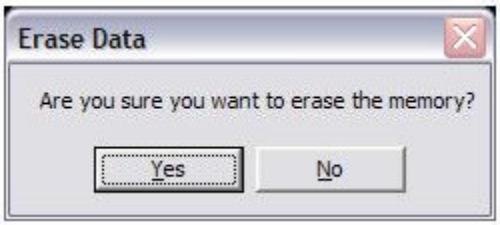
While downloading from memory, you can observe the data being transferred in the graph area. When the computer has downloaded all the data from memory, a long beep will indicate the download process has finished. An "Erase Data" window will appear asking if you want to erase the memory from the User Unit. To erase the memory, click "Yes," otherwise click "No". When you click "Yes" to erase the memory on the device, a series of beeps will indicate that the memory is being erased. The deletion is complete when the beeps stop.

Switching Data Modes

To **switch back to wireless data acquisition from USB**, you must turn off and remove the USB cable from the device. When you turn on the device again, you should hear a series of beep indicating the startup of the device and transition into wireless mode.

To **switch to USB data aquisiton from wireless mode**, you must first turn on the device. There will be a series of beeps during the start-up routine. Wait for these to stop, then plug in the USB data cable into your device. You should hear two beeps after you plug in the cable. The beeps indicate that the device is switching from wireless mode to USB data mode.

Erasing Memory



While you are in USB data mode, you can erase the memory at anytime by clicking on "Erase Memory" button on the tool bar menu. A window dialog appears to ensure you want to erase the memory. Clicking "Yes" will continue the process of erasing the memory. A series of beeps will follow, indicating the memory is erasing. The process is finished when the beep pattern stops. Clicking "No" will cancel the process.

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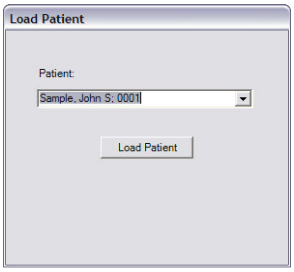
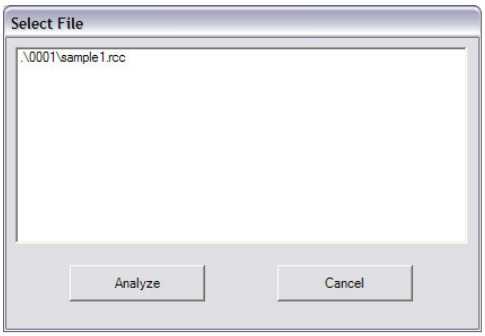
Reviewing Saved Data

Saved data can be reviewed at a later time by clicking the "Review Saved Data" button.

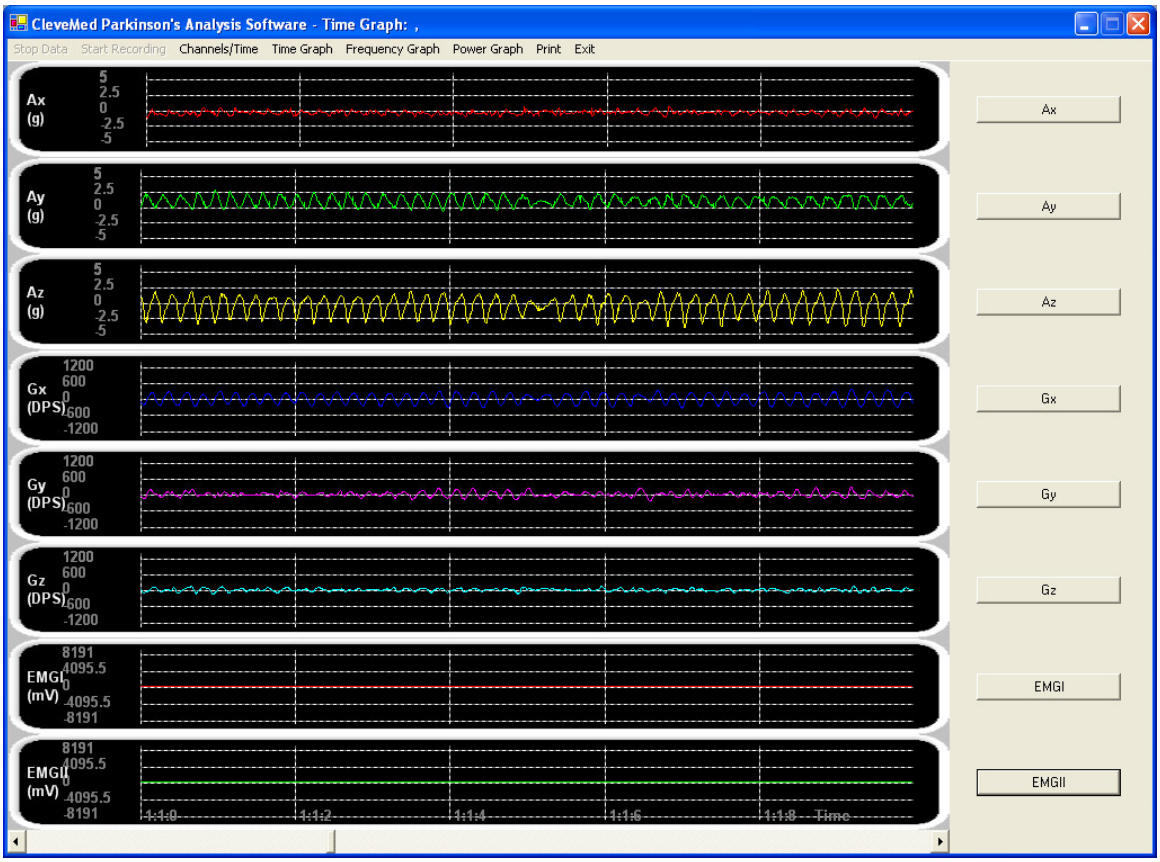


Clicking this will bring up a Load Patient window. Use the pull down menu to find the patient's name and then click Load Patient.

After clicking Load Patient, a second window appears prompting you to select a file. Choose the file to review and click "Analyze."



After indicating the file to be reviewed, the recorded data will appear for analysis. The data display format that you are observing is the "Time Graph". Use the scroll bar to examine the data. The scroll bar will scroll across hours/minutes/seconds of the data you collected.



The data you collected can be display in three different formats by using the toolbar menu of Review Saved Data. The data can be display as time graph, frequency graph, and as power graph.

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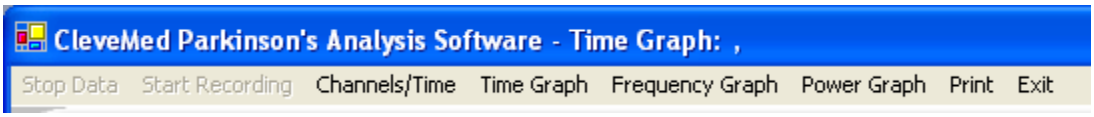
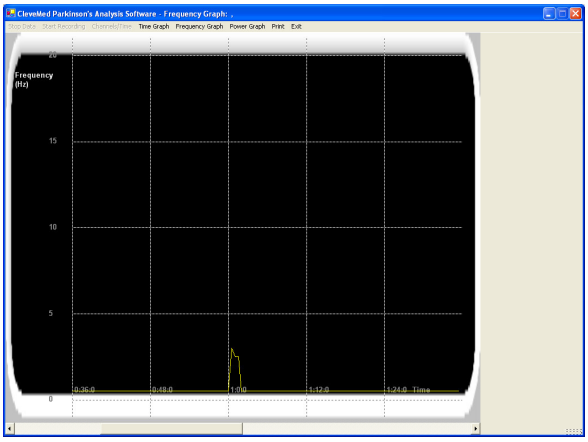
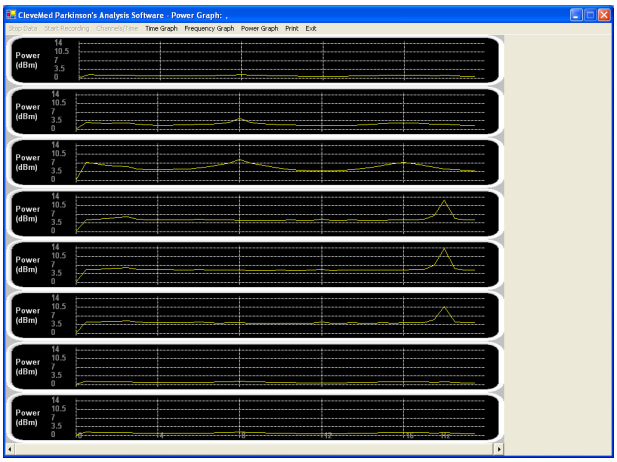


To view the data you collected as frequency graph, simply click on "Frequency Graph" of the toolbar menu. There's a brief wait period before the data can be display as frequency graph. The wait period depend on how much data is to be processed. For 12 hours of data, the expected wait time would be around 1.5 minutes to 3 minutes.

In "Frequency Graph" display format, you can scroll across hours/minutes/seconds to view the peak frequency of the subject's movement over time. The peak frequency is calculated over 30 second windows and plotted in the graph. The image display below is an example of what you would see when you are in "Frequency Graph" display option.



The data you collected can also be displayed as a Power Graph. To display the data collected as Power Graph, simply click on "Power Graph" on the toolbar menu. . There's a brief wait period before the data can be display as Power Graph. The wait period depend on how much data is to be processed. For 12 hours of data, the expected wait time would be around 1.5 minutes to 3 minutes. An example of what you would see is shown below.



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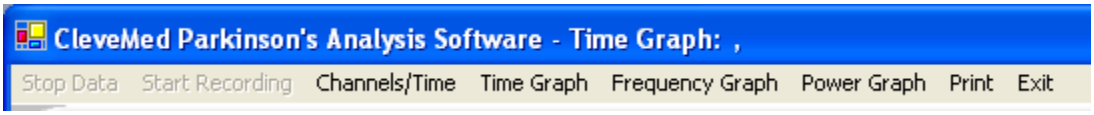
Once your data is processed for “Frequency Graph” or “Power Graph”, you can switch between the three display formats without processing the collected data again. You can use the toolbar menu to switch between Time Graph, Frequency Graph, and Power Graph. If you exit “Review Saved Window”, your data will have to be processed again for “Frequency Graph” and “Power Graph”, the next time you use these functions.

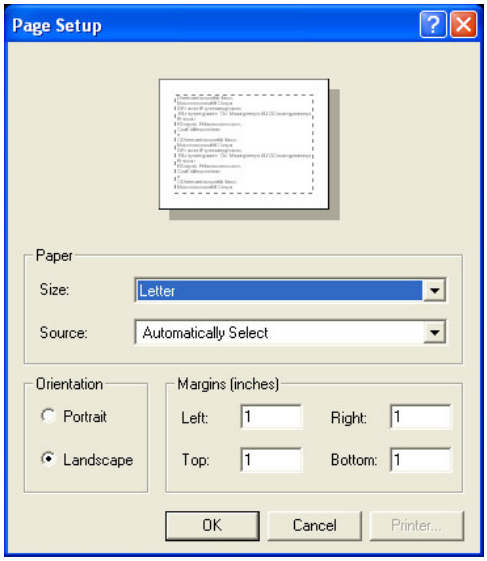
To exit Review Saved Data window, click on Exit on the toolbar.

Printing Current Graph

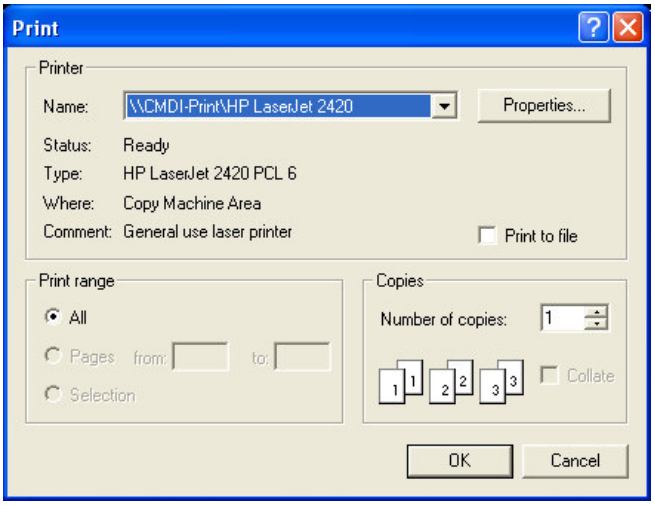
You can print the current view of the graph display in both “Review Saved Data” and “Collect Data” window. To print the current graph in “Collect Data” or “Review Saved Data”, simply click on “Print” on the toolbar menu.



A new window will appear upon clicking on “Print” called Page Setup. From Page Setup, you can select the paper size, margins, paper source, and orientation of the print. After you have selected the pint option, hit OK to continue.



After you have clicked OK from the previous window, a new window will appear for you to select a printer of your choice. The image below is an example of what you would see. After you have selected the desired printer to print the graph, click OK to proceed with the printing. To cancel the print process, click on Cancel of this window.



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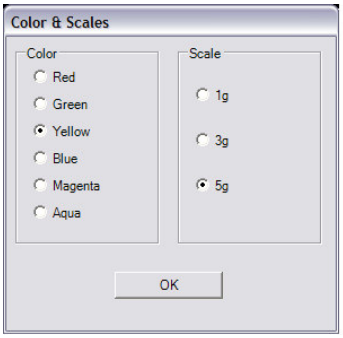
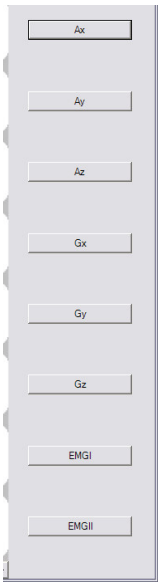
Graph Color and Scale Setup

The graph color and scale can be changed in both the Collect Data window and the Review Saved Data window. To access this menu, click on the graph title button to the right of the graph. This will bring up the Color and Scales window.

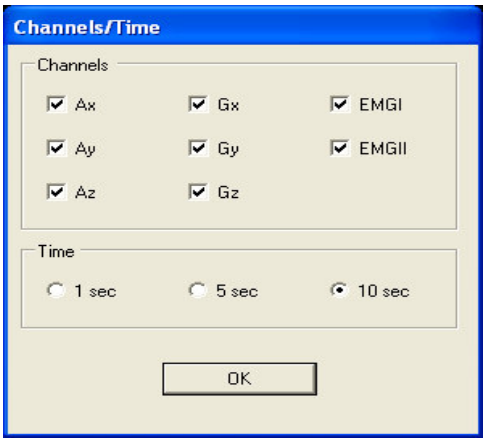


Different color and scale options are available. Click on the desired color or scale number, and then click "OK" to return to the data window.



Channels / Time

The number of visible graphs and their scales can be changed in both the Collect Data window and the Review Saved Data window. To access this menu, click on the "Channels/Time" button on the toolbar. This will pull up the Channels/Time Scales window. Different visible channels and time scale options are available. The checked the channels will be visible. Choose your desired visible channels and time scale. Click "OK" to save your changes and return to the graph window.



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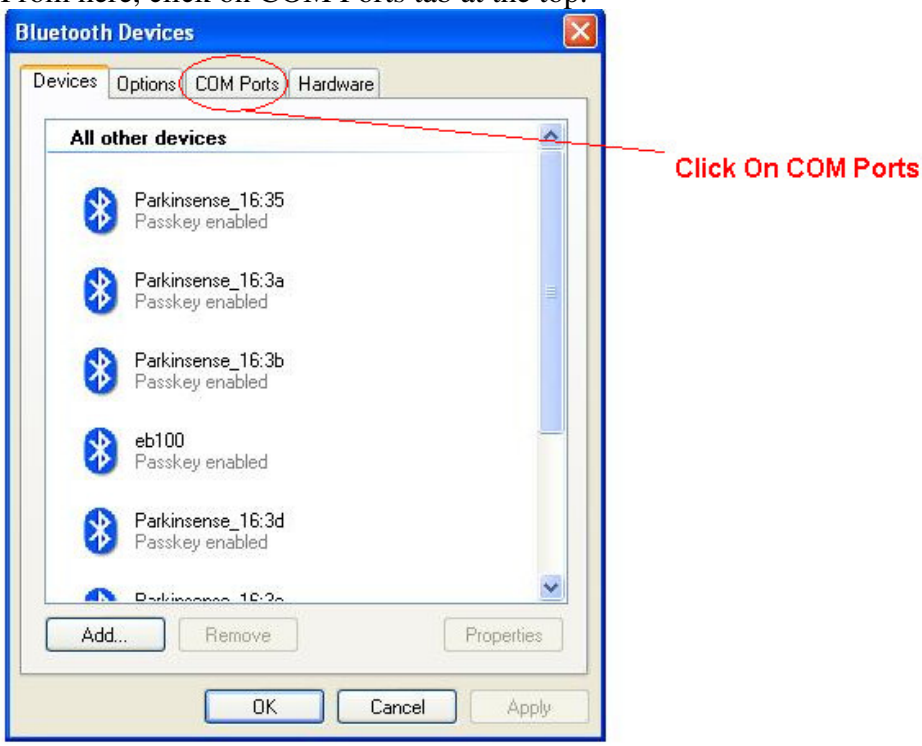
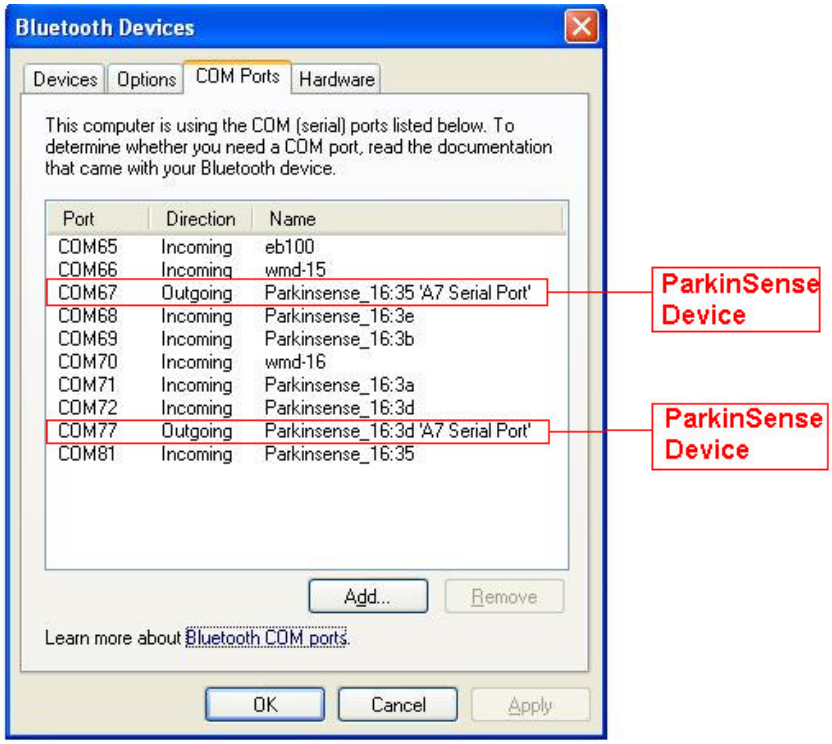
Miscellaneous Information:

Obtaining a Bluetooth port manually:

1. Turn on the ParkinSense User Unit. A series of beeps indicates that the device is on and ready for wireless data transmission.
2. Plug the Bluetooth Device into the USB port
3. Go to your blue tooth Devices Manager by going to
   Start → Control Panel → Bluetooth Devices

4. Double click on Bluetooth Devices to enter the Bluetooth Devices Manager.
5. From here, click on COM Ports tab at the top.



6. The system will do a scan and return a list of devices found, as well as the associated ports. Your ParkinSense radio is found in any ports labeled "A7 Serial Port."

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