

SmartStep™ Clinic

User's Manual



Andante Medical Devices Ltd

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About this Document

This document describes the SmartStep™ insole, Control Unit, and software, used for the assessment and training of walking pathologies. The document is intended for therapists treating patients with walking pathologies.

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Style Conventions

Convention	Used for
Verdana	Regular text.
Arial Bold	Names of menus, commands, buttons, and other elements of the user interface.
<i>Arial Italics</i>	Special terms, the first time they appear.
Monospace	Text entered by a user, values of parameters, and usage examples.
	Notes , which offer an additional explanation or a hint on how to overcome a common problem.

About this Document



Warnings, which indicate potentially damaging user operations and explain how to avoid them.

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Intended Use

SmartStep™ is intended to measure the weight applied to the plantar surface of the affected limb during rehabilitation. The device alerts the patient and/or therapist with a beeping sound when the weight exceeds a pre-determined maximum level. SmartStep™ produces objective examination, training and monitoring of gait outcomes, using accurate analysis as well as audio and visual feedback.

Technical Specifications

Control Unit	General	Dimensions	110 x 68 x 48 mm
		Weight	215 g
		Operating Time	Approx. 5 Hours (Full battery, max load)
		Charging Time	Approx. 10 Hours (Empty battery)
Battery	Operating Voltage	3.6 VDC	
	Type	Ni-MH Rechargeable battery	
	Capacity	700 mAh	
	Power Consumption	0.5 W	
Indicators	Mode of Operation	7 Segment	
	Charging	Green LED	
	Low Battery	Orange LED	
Memory	Capacity	128 KB	
	Type	Rewritable	
	Max record time	Approx. 10 Minutes	
	No. of Logged files	1	
Connectors	Input Type	RJ-11	
	Input Uses	Charging	
Communication	Type	Wireless	
	Protocol	Bluetooth ver. 1.1 certified	
	Transmission frequency	2.4 GHz	
	Output Power	0 dBm (Class 2)	
	Maximum distance	10 m / 30 ft	
Environmental Conditions	Operating Temperature	10 °C to 40 °C	
	Storage Temperature	-5 °C to 50 °C	
	Operating Humidity	30% - 75%	

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Charger	General	Manufacturer	GlobTek Inc.
		Model	GT-A81051-0509UW2
		Dimensions	54.0 x 40.0 x 29.5 mm
		Weight	90 g
		Input Voltage	90 Vac to 264 Vac
		Output Voltage	9 VDC
		Max. Output Power	5 W
		Standard	UL 60950, CUL, CLASS II FCC Part 15 CLASS B
		Sensors	General
Compensation	Temperature Compensated Over -40° to $+125^{\circ}\text{C}$		
Operating Characteristics	Pressure Range		0 – 250 kPa
	Supply Voltage		5 VDC
	Supply Current		7 mA
	Sensitivity		18 mV/kPa

Warnings, Precautions and Limitations

Please read, understand, and follow the precautionary and operating instructions:

Limitations

SmartStep™ is a biofeedback device and does not prevent injury. Therefore if the patient feels any pain or discomfort while using the device he should stop using the device immediately and consult a physician.

- Andante Medical Devices Ltd is NOT responsible for any damages that occur as a result of the misuse of this device.
- Physician or therapist must check very high arches in their patients. In cases of a high arch, system accuracy will be reduced.
- SmartStep™ should only be used in accordance with the exercise options provided in the software and should not be used while running, jumping, etc.
- Weight limits should be set by qualified personal and not by the patient.
- A patient with hearing loss, particularly in the higher frequencies should not use this device as he may not be able to hear the audio feedback tone.
- SmartStep™ is designed for use with sports shoes only. Do not use with other types of shoes.
- Patients must wear socks during sessions. SmartStep™ should not be used by barefoot patients.
- SmartStep™ should not be used in cases of:
 - Non-weight bearing prescription.
 - Activity limitations due to medical disorder, medication, or emotional conditions.
 - Vascular insufficiencies or infection.
 - Severe cognitive disabilities.

Warning and Precautions

Control Unit



Never try to connect any other device and/or cable to the **Charging** connector of the Control Unit (e.g. telephone device or cables).



The plastic cover used to seal the **Charging** connector should never be removed while the unit is on the patient's leg. The cover should only be removed when charging the unit.



When charging the Control Unit, the unit and its strap must be removed from the patient's leg.



This equipment has been approved for mobile applications where the equipment should be used at distances greater than 20cm from the human body (with the exception of hands, wrists, feet and ankles). Operation at distances less than 20cm is strictly prohibited.

- Protect the Control Unit from any contact with water, such as dampness from sinks, bathtubs and shower stalls, or wet weather such as rain or snow. Do not use water or any other liquids to clean the Control Unit.
- Shock or impact may damage the Control Unit.
- The Control Unit should be operated, transported, and stored within a temperature range of 10-40°C, (50-86°F) and a relative humidity of 30-75%.
- Do not open the Control Unit case. Only an Andante Medical Devices technician is authorized to disassemble the device.

Important Charging Information



Only use the charger provided with your SmartStep™ system. Do not substitute with any other charger. Use of another charger could cause batteries to explode and possible serious injury.



Charging must be done outside the patient environment and should be obtain in the medical used room.

- Do not operate the charger with a damaged cord or plug. If damaged, have the charger replaced immediately by a qualified service technician. Following this rule will reduce the risk of electric shock, fire, or serious personal injury.
- Do not disassemble the charger. Only an Andante Medical Devices technician is authorized to take the device a part.
- Do not use the charger if it has received a sharp blow, been dropped, or otherwise damaged in any way. Consult an Andante service technician to replace the charger. Following this rule will reduce the risk of electric shock, fire, or serious personal injury.
- When the charger is not in use, disconnect it from the power source. Do not leave the battery connected to charger for longer than a week, since overcharging may shorten its lifespan. If left unused, a fully charged battery will discharge itself over time.

Important Battery Information



There is a risk of explosion if battery is replaced by an incorrect type.

For disposal and replacement of a used battery, consult an authorized Andante service technician.

- The Control Unit is powered by a rechargeable NiMH battery. Note that a new NiMH battery's full performance is achieved only after two or three complete charge and discharge cycles.
- The battery can be charged and discharged hundreds of times but it will eventually wear out. When the operating time is noticeably shorter than normal, it is time to replace the battery.
- Do not try to remove the battery. Contact qualified service personnel to change the battery when needed.

Computer



The computer should be at least 1.5m away from the patient.



The therapist must not touch the computer and the patient simultaneously

Insole

- The insole must fit the shoe size. Shoes that are too tight may result in inaccurate readings. Please note that shoe sizes vary according to manufacturers.
- It is advised to change the insole once every three months. If insole use extends beyond three months, system accuracy may be affected. You will find a replacement parts order form at the end of this document.
- Due to risk of transferable infections, it is highly recommended not to transfer this insole to other users.

General



The SmartStep™ system is to be used under the supervision of a physician or licensed health care provider such as a physiotherapist in rehabilitation units or clinics.



The system is intended for indoor operation only.

- Use of SmartStep™ outside the optimal range of operation (15-80 Kg) may lead to reduced accuracy of about 10%.
- Always ensure that shoelaces are tightly tied and do not become tangled up with the pneumatic tubes or other components.
- An improperly fitted shoe could result in distorted readings or injury.
- Only use SmartStep™ on solid surfaces. Avoid rugged, uneven terrain or steep inclines.
- Do not operate SmartStep™ on slick or wet surfaces.
- Environments with excessive dirt, humidity, dust or debris may damage SmartStep™.



US Federal Law restricts this device to sale by or on the order of a physician.

Classification

- **Type of protection against electric shock** –
- When the unit is at normal operation: Internally powered equipment.
- When the unit is at charging: Class II.



- **Degree of protection against electric shock** – Type BF applied part.
- **Classification according to the degree of protection against ingress of water** – Ordinary.
- **Sterilization or disinfection** – Not required.
- **Equipment not suitable for use in presence of flammable mixture with air, or with oxygen, or with nitrous oxide.**
- **Mode of operation** – Continuous operation.

Regulatory Compliance

The SmartStep system was tested and found to be in compliance with the following standards:

Safety

- IEC 60601-1
- IEC 60601-1-1

EMC (Electromagnetic Compatibility)

- IEC 60601-1-2
- ETSI EN 301 489-1 V1.5.1 (2004-09)
- EN 55011 : 2003
- FCC Part 15.247

FCC Statements:

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC ID: TWMSMARTSTEP0106

Care and Maintenance

- Keep Control Unit and accessories out of reach of small children.
- Keep Control Unit and accessories dry. Precipitation, humidity, and liquids contain minerals that will corrode electronic circuits.
- Do not use or store Control Unit or accessories in dusty or dirty areas.
- Do not store Control Unit or accessories in hot areas. High temperatures can shorten the lifespan of electronic devices, damage batteries, and warp or melt certain plastics.
- Don't store Control Unit or accessories in cold areas. When the Control Unit warms up (to its normal temperature), moisture can form inside the Control Unit, which may damage electronic circuit boards.
- Don't drop, knock, or shake the Control Unit. Rough handling can break internal circuit boards.
- Don't use harsh chemicals, cleaning solvents, or strong detergents to clean parts or accessories. Wipe with a soft cloth slightly dampened in a mild soap and water solution.

1 Introduction

SmartStep™ was developed to assist clinicians to accurately assess, treat, and track the rehabilitation of patients who are undergoing gait training, following orthopedic or neurological impairment.

1.1 Objective Assessment

SmartStep™ improves the objective assessment of different aspects of gait outcomes, by accurately measuring the ground reaction force exerted by the patient during different kinds of exercises.

1.2 Training

SmartStep™ provide precise feedback in both visual and audio modes. This procedure enhances the learning process and improves movement control (weight and timing) and helps to normalize gait patterns.

1.3 Rehabilitation Tracking

The SmartStep™ system records the assessment and training sessions. Historical data is collected and saved in each session for future examination.

The system allows you to:

1. Easily retrieve past sessions.
2. Analyze past sessions.
3. Compare patient sessions in order to track rehabilitation.

1.4 Using SmartStep™ in Online and Offline Mode

In assessment as well as training, the SmartStep System can be used in online or offline mode.

- In online mode, SmartStep™ communicates with your computer to provide real-time visual feedback. Audio feedback is also possible. During an online session, it is recommended to work in the vicinity of the computer (in a 7m radius).
- In offline mode, SmartStep™ provide real-time audio feedback. It is possible to records session data, and downloaded it to the computer for later analysis.

2 System Description

2.1 SmartStep™ Kit Contents



The SmartStep™ Kit

The SmartStep™ kit contains the following items:

1. 3 insoles in: European sizes 37/8, 41/2 and 43/4
or US sizes 6/7, 8.5/10 and 10.5/11.5.
2. Control Unit with strap (which includes a plastic cover for the Charging connector).
3. Manual pump.
4. Battery charger for the Control Unit
5. SmartStep software CD.
6. Bluetooth USB adapter.
7. Bluetooth USB adaptor driver installation CD.
8. Quick User's guide.

If any of the above items are missing, or appear damaged, please contact your supplier.

2.2 SmartStep™ Components

SmartStep™ consists of four main components: An insole, Control Unit, software and a manual pump. The following sections explain each of these components in more detail.

2.2.1 Insole



Insole

The SmartStep™ insole is placed inside the patient's shoe, and is used to measure the force exerted by the patient on the foot, during an assessment or a training session.

The insole contains two inflatable compartments – the forefoot and the hind foot. Each compartment is connected, via a tube, to a pressure sensor. When a patient exerts force on the leg, increased air is driven out of the air pockets and is detected by the pressure sensors and converted into uneven weight in Kg/lb.

SmartStep™ sessions are performed on a single foot at a time. The insole is suitable for both left and right feet. It is supplied in a range of sizes (see details in 2.1 above).

2.2.2 Control Unit



The Control Unit

The SmartStep™ Control Unit serves three purposes:

- **Data relay** to a computer via wireless (Bluetooth) communication. The computer must have the SmartStep™ software installed (see 3.2). Connecting the Control Unit to a computer allows you to view a graph of the gait pattern, as the patient performs an online workout.
- **Feedback generation** when the patient reaches and exceeds the desired weight range. Audio feedback is optional; it can be turned on and off by toggling the Control Unit's operation mode.
- **Optional data collection** in an offline mode that can be turned on or off by toggling the Control Unit's operating mode. The collected data can be downloaded to a computer and view session statistics and graphs.

System Description

Control Unit

Control Unit Modes of Operation

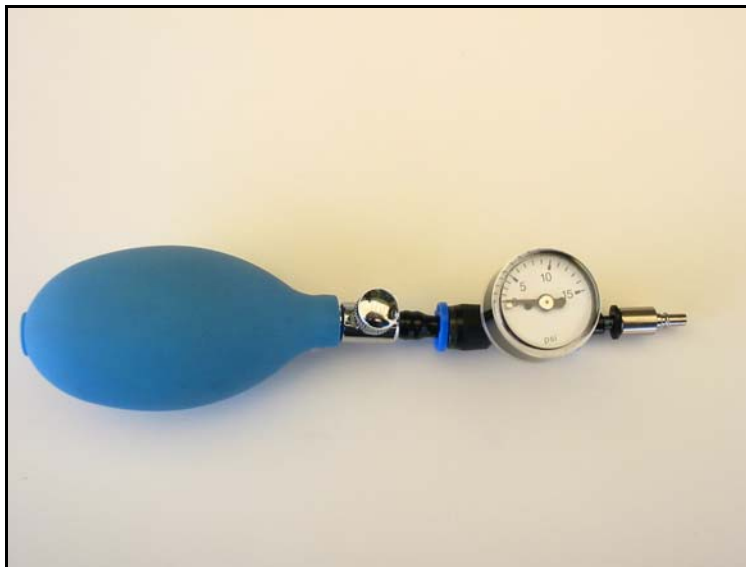
Operation mode	Name	Description
0	On	Control Unit is on.
1	Online Assessment	Online assessment mode (when no weight thresholds are determined) with graphic visual feedback of patient performance.
1.	Offline Assessment and Data collection	Offline assessment mode (when no weight thresholds are determined). Data is collected. Later it is possible to save it in the patient's file.
2	Online/Offline Training	Online/Offline training mode (when weight thresholds are determined). Audio feedback is available in the form of beeps to alert patient and/or therapist to weight exerted by the patient. In Online mode graphic visual feedback is available as well.
2.	Offline Training and Data collection	Offline training mode (when weight thresholds are determined). Data is collected. Later it is possible to save it in the patient's file. Audio feedback is available in the form of beeps to alert the patient and/or therapist to weight exerted by the patient.
4	Download Completed	Data collected offline has successfully been downloaded to the computer. After a pause, mode reverts to 1 or 2 (without the dot, depending on the mode before the download process).
4.	Download in Progress	Data collected offline is being downloaded to the computer. When download is complete, the mode reverts to 4 (without the dot).
E	Air Pressure Error	Incorrect initial air pressure.
C	Wireless Error	Wireless connection was lost.
S	Sensor Problem	Sensor error detected.
P	Low Air Pressure	Air pressure is lost in insole compartments (hind and/or fore).
H	Maximum Values Exceeded	System exceeded maximum values.
L	Low Battery	The unit is turned off automatically.

2.2.3 SmartStep™ Software

The desktop software is used to perform the following functions:

- Monitor gait parameters.
- Display visual feedback.
- Show results and statistics from Online/Offline sessions.
- Track rehabilitation progress.

2.2.4 Manual Pump



The Manual Pump

The manual pump is designed to inflate the two compartments with air. The manual pump is not connected directly to the insole. The inflation is done via the Control Unit.

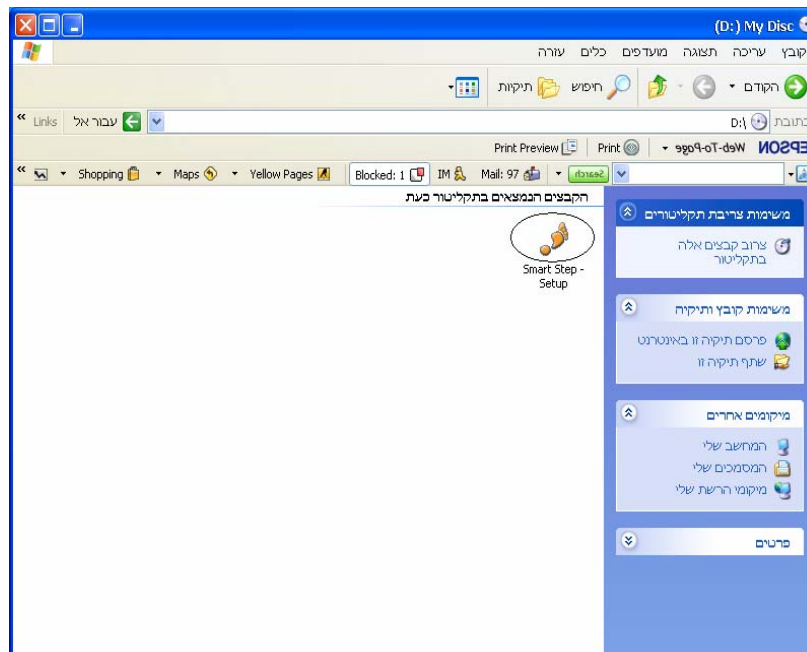
3 Installation

3.1 System Requirements

- Microsoft Windows® XP Professional or Home Edition.
- 128 MB of RAM minimum, 256 MB or greater recommended.
- Up to 20 MB of available hard-disk space.

3.2 SmartStep Software Installation

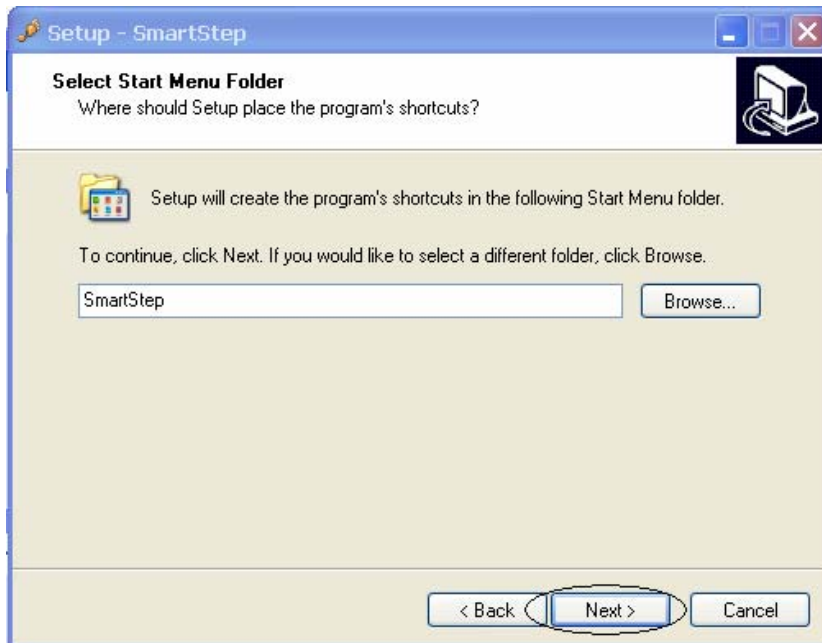
1. Insert the SmartStep Installation disk into the CD-ROM drive.
2. Open the CD-ROM root folder and double click on the SmartStep icon.



3. Click **Next**.



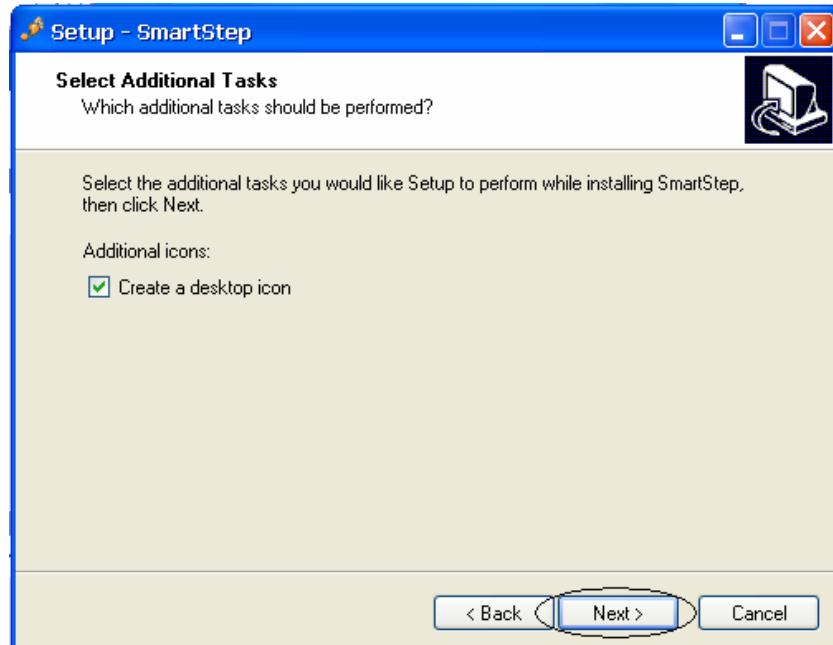
4. It is recommended to use the default destination folder. Click **Next**.



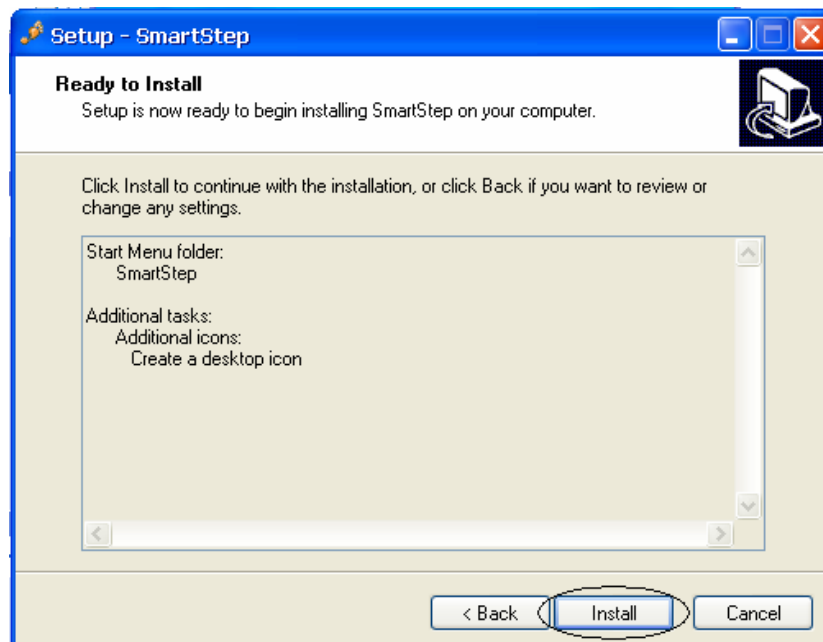
Installation

SmartStep Software Installation

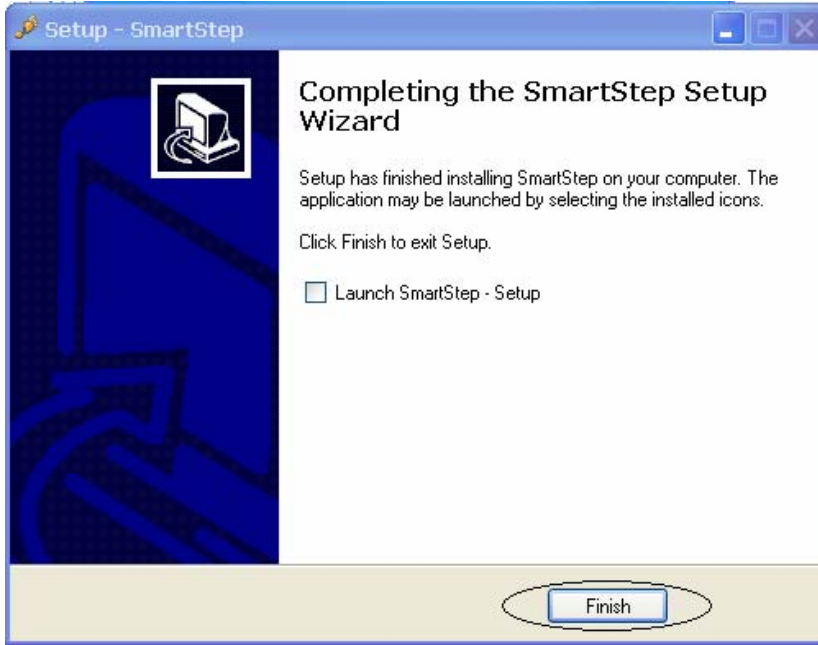
5. It is recommended to check the **Create a desktop icon** check-box. Click **Next**.



6. Click **Install**.



7. Click **Finish**.



SmartStep installation is now complete. The next step is the Bluetooth USB Adapter installation.

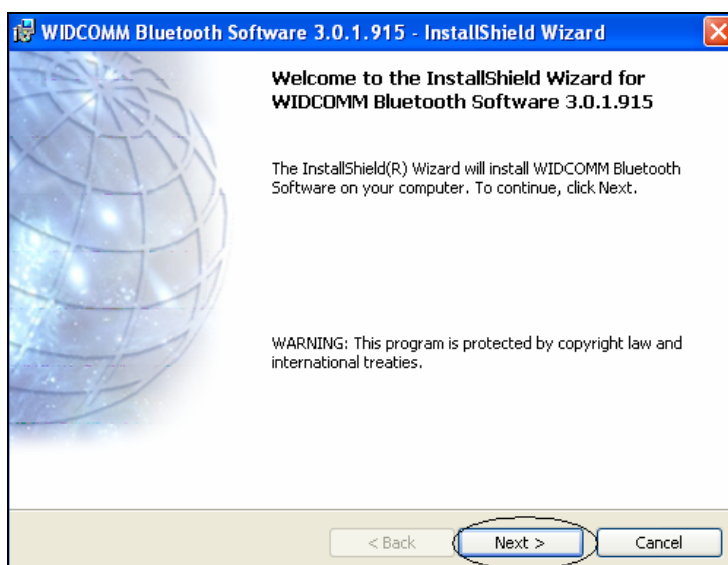
3.3 Bluetooth USB Adapter Driver Installation

 To avoid software installation problems, please do NOT insert the Bluetooth USB Adapter until the installation displays a message to do so (step8).

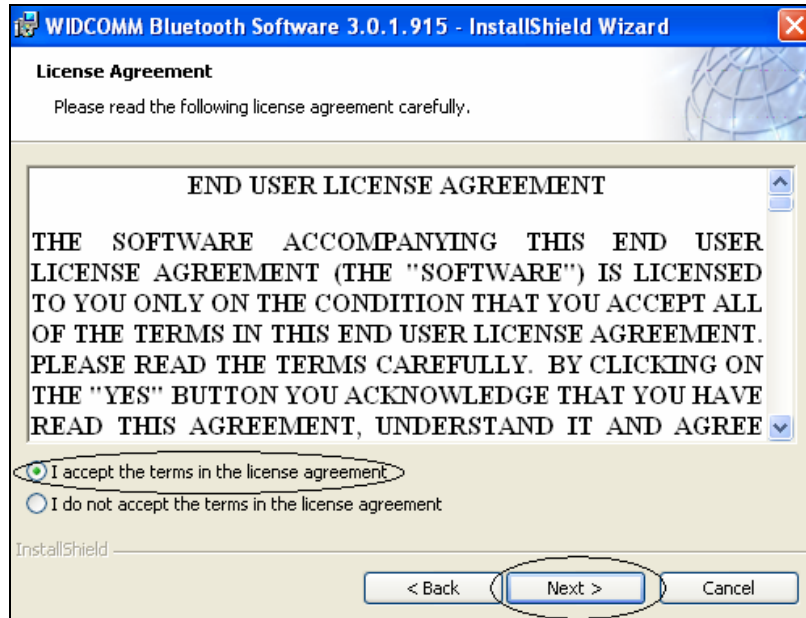
1. Insert the USB Adapter installation disk into the CD-ROM drive. The Setup program should launch automatically. Click the **Install Software** button.



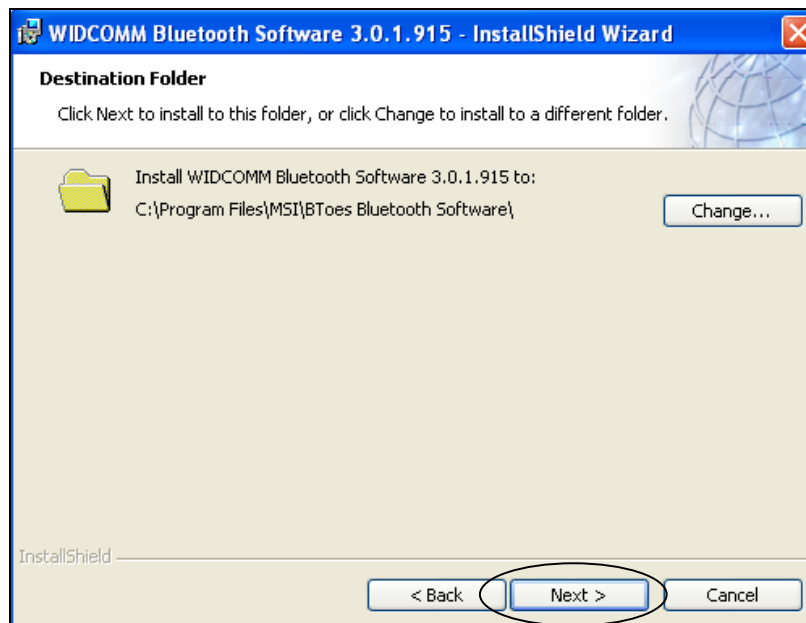
2. Click the **Next** button.



3. Choose the **I accept...** option, and click the **Next** button.



4. In this screen it is possible to change the destination folder by clicking the **Change...** button. It is recommended to use the default destination folder. Click **Next**.



Installation

Bluetooth USB Adapter Driver Installation

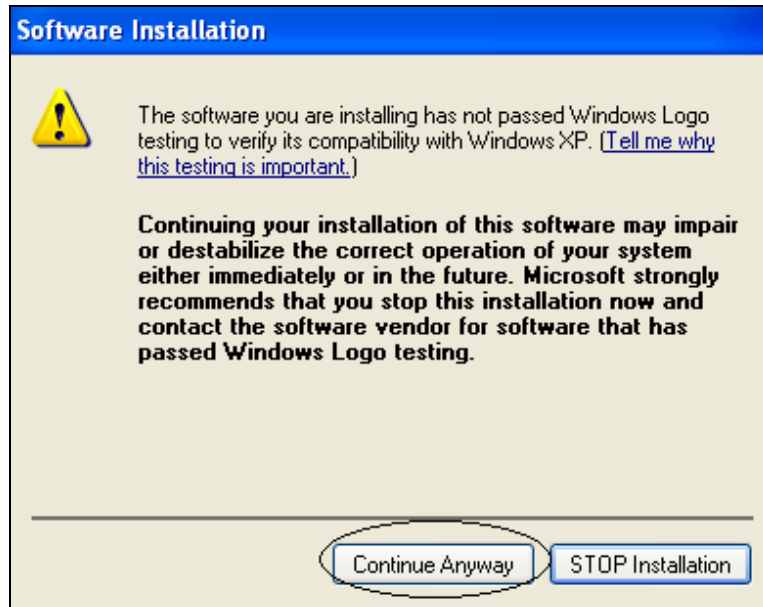
5. Click **Install**. The installation might take several minutes.



6. If the dialog below opens, click **Cancel**.



7. If the dialog below opens, click on the **Continue Anyway** button.



8. A message box indicating that **No Bluetooth device was detected** should popup. Please insert the Bluetooth USB adapter and click **OK**.



Installation

Bluetooth USB Adapter Driver Installation

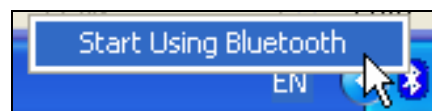
9. Click **Finish**.



10. Click **Exit**.



11. Double click on the **My Bluetooth Places** icon on the desktop. It is also possible to double click the Bluetooth icon that is located in the notification area of the taskbar, or to right click it and select **Start Using Bluetooth**.



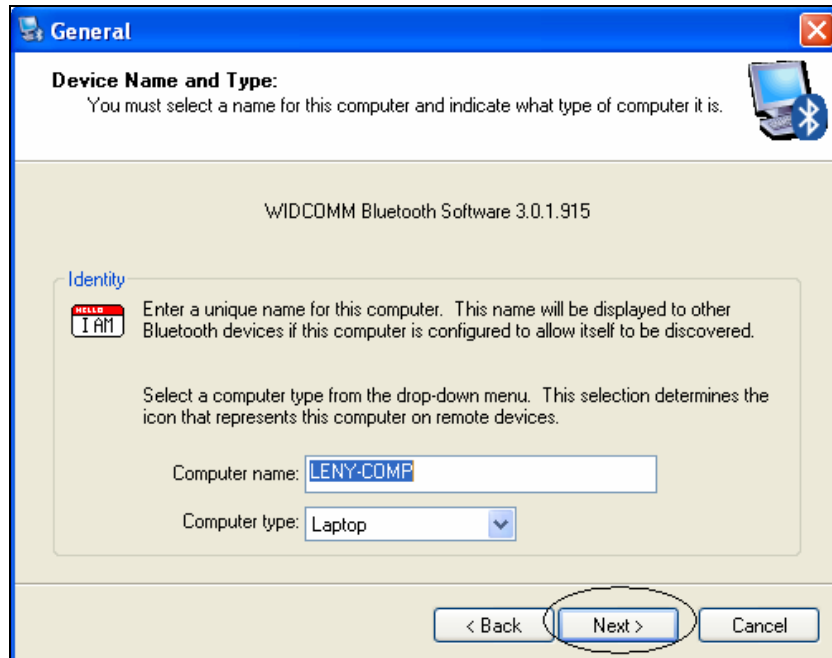
12. Click **Next**.



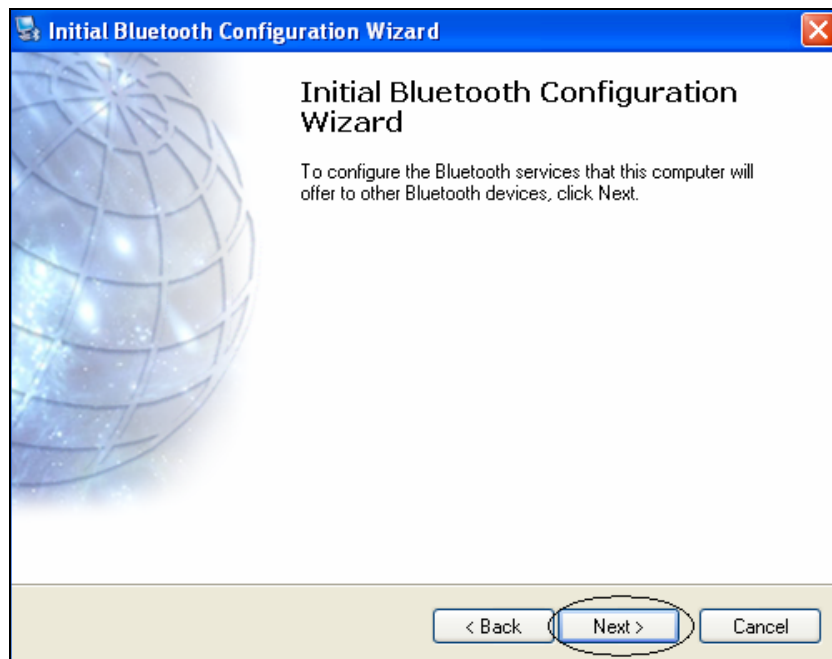
Installation

Bluetooth USB Adapter Driver Installation

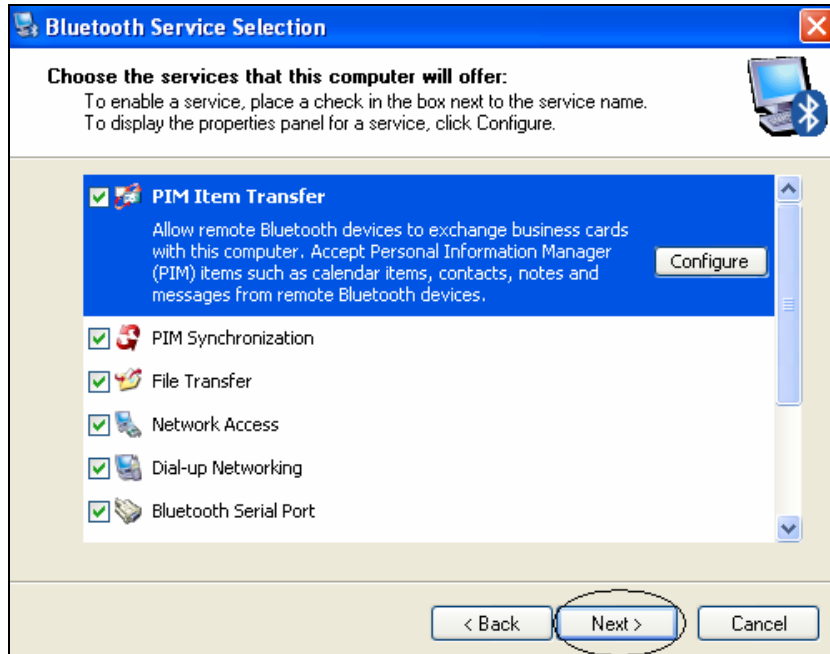
13. Click **Next**.



14. Click **Next**.



15. Leave the default settings. Click **Next**.



16. Click **Skip**.



Installation

Bluetooth USB Adapter Driver Installation

17. Click **Finish**.

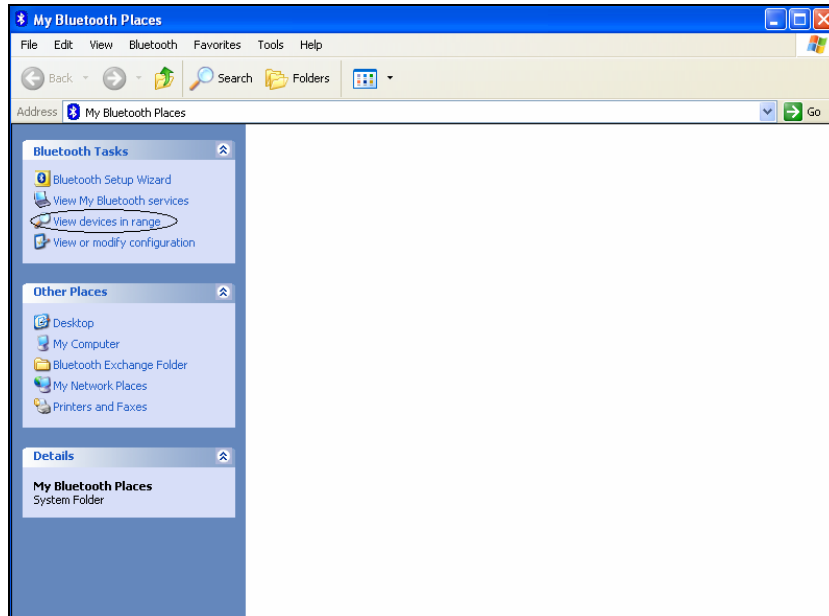


18. Double click the **My Bluetooth Places** icon on the desktop.



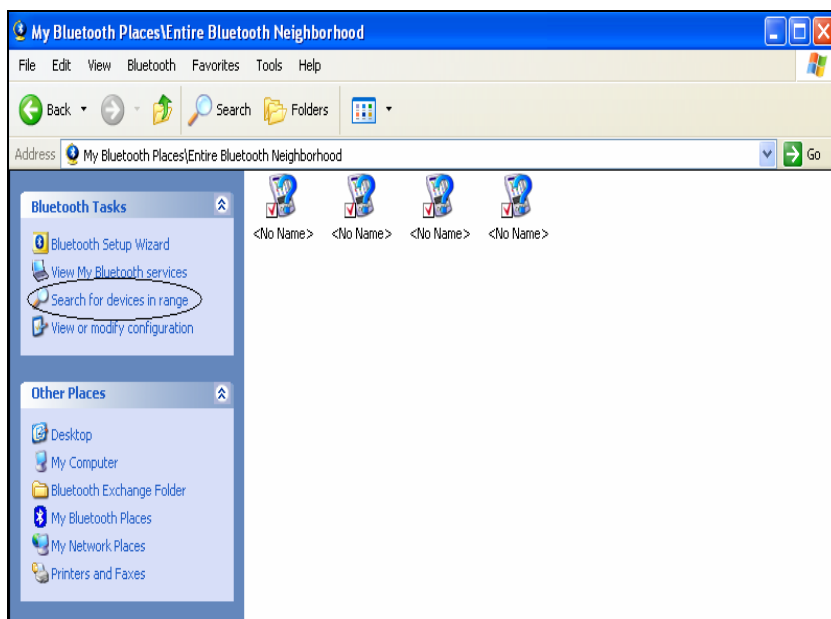
19. Turn the **Control Unit** on.

In the **Bluetooth Tasks** menu, click the **View Devices in Range** option.



20. The list should contain only devices that were already connected to the computer.

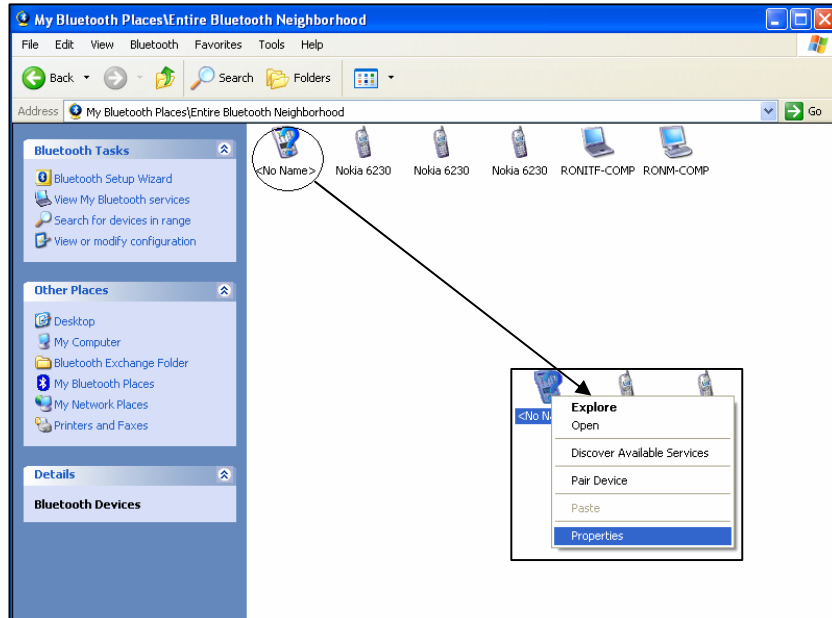
In the **Bluetooth Tasks** menu click the **Search for Devices in Range** option.



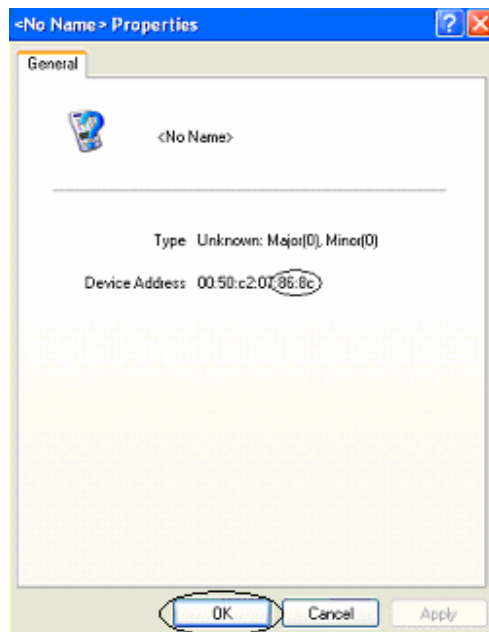
Installation

Bluetooth USB Adapter Driver Installation

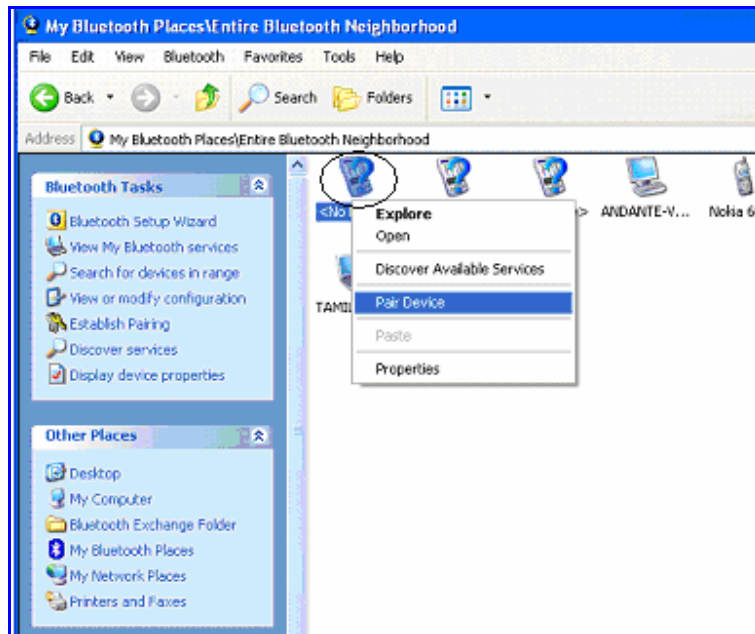
21. Right-click the icon marked with the circle (the icon with the question mark on) .
Choose the **Properties** option.



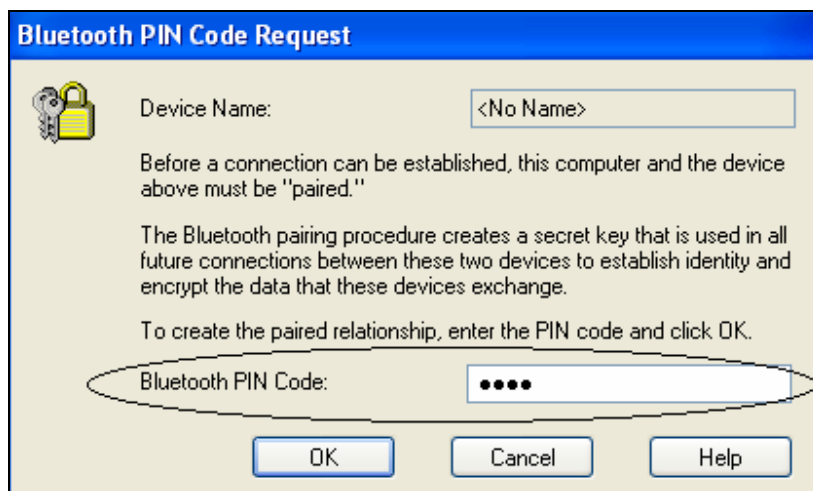
22. Make sure that the device address matches the address on the back of the Control Unit. The 4 characters marked in the screenshot are the **Bluetooth Pin Code**. Close the window by clicking **OK**.



23. Right click the icon marked with the circle (the icon with the question mark on). Choose the **Pair Device** option.



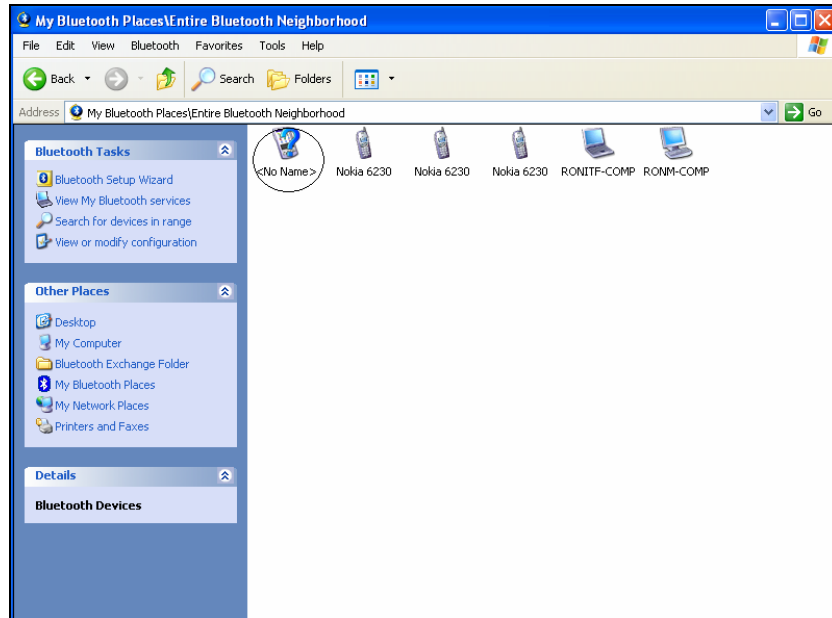
24. Enter the four letter **Bluetooth Pin Code** (marked in the screenshot in step 22). Use capital letters only. Click **OK**.



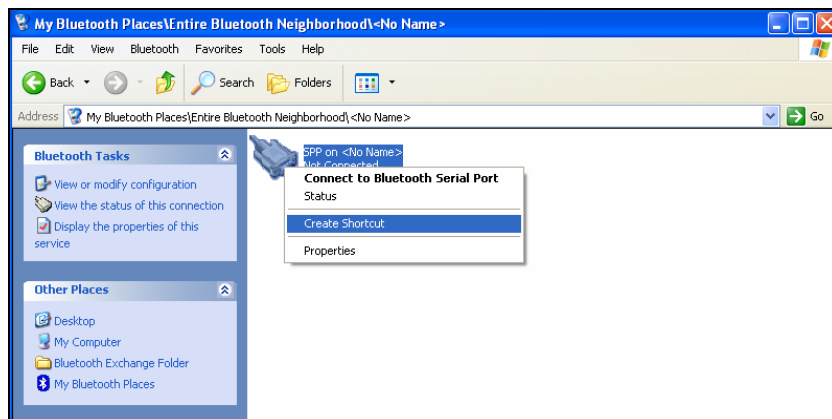
Installation

Bluetooth USB Adapter Driver Installation

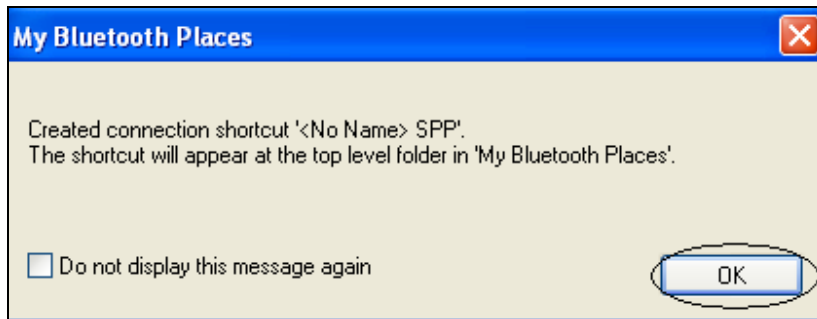
25. Double click the icon marked with a circle (the icon with the question mark on).



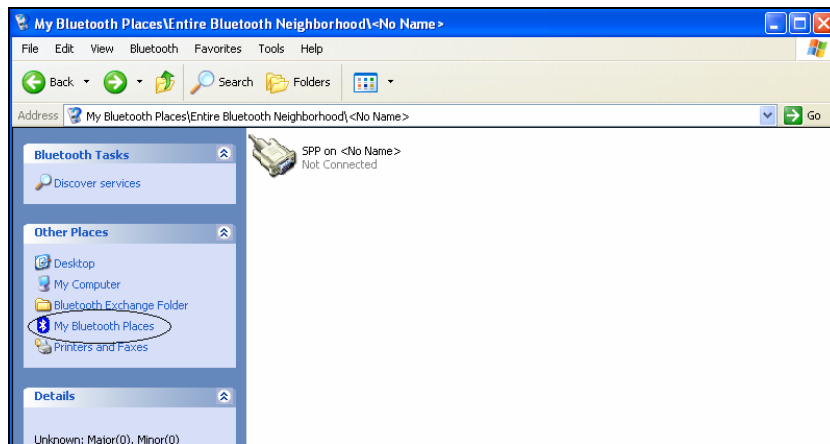
26. Right click the icon below and choose the **Create Shortcut** option.



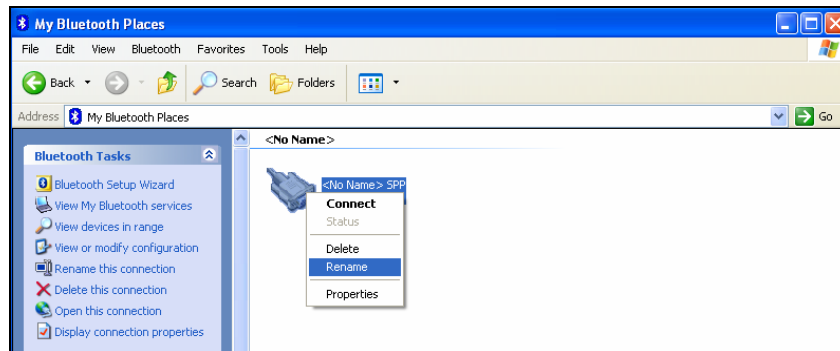
27. Click the **OK** button.



28. Choose the **My Bluetooth Places** option, in the **Other Places** menu.



29. Right-click the marked icon, and **Rename** it for later easy recognition.

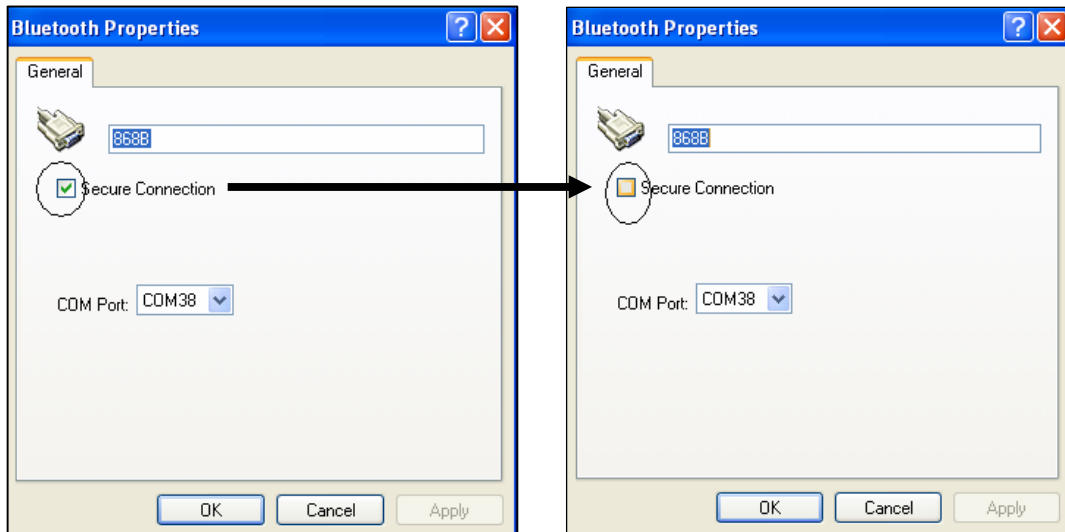


Installation

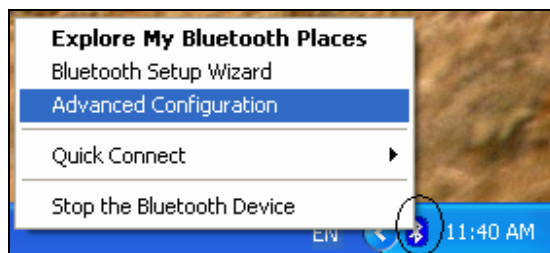
Bluetooth USB Adapter Driver Installation

30. Right-click the marked icon again, and choose the **Properties** option.

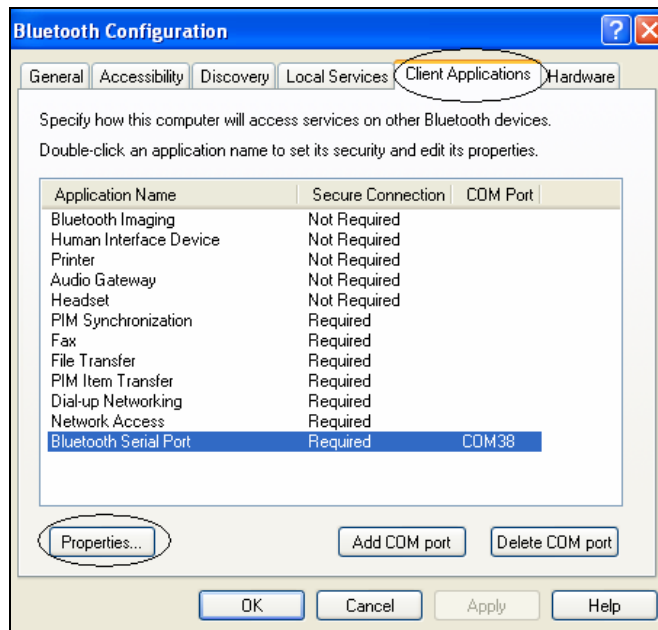
31. Uncheck the **Secure Connection** checkbox. Click **OK**.



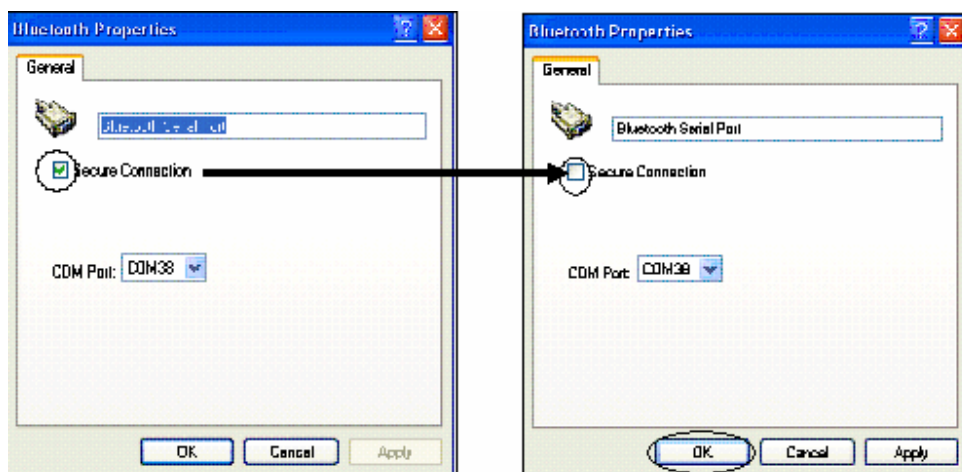
32. In the **Taskbar** notification area right-click the marked icon. Choose the **Advanced Configuration** option.



33. Select the **Client Applications** tab. Select the **Bluetooth Serial Port** list item and click the **Properties...** button.



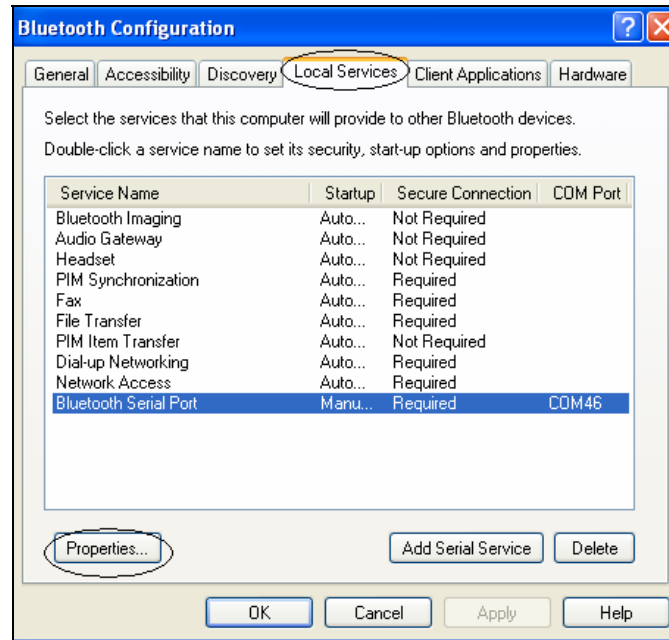
34. Uncheck the **Secure Connection** checkbox. Click **OK**.



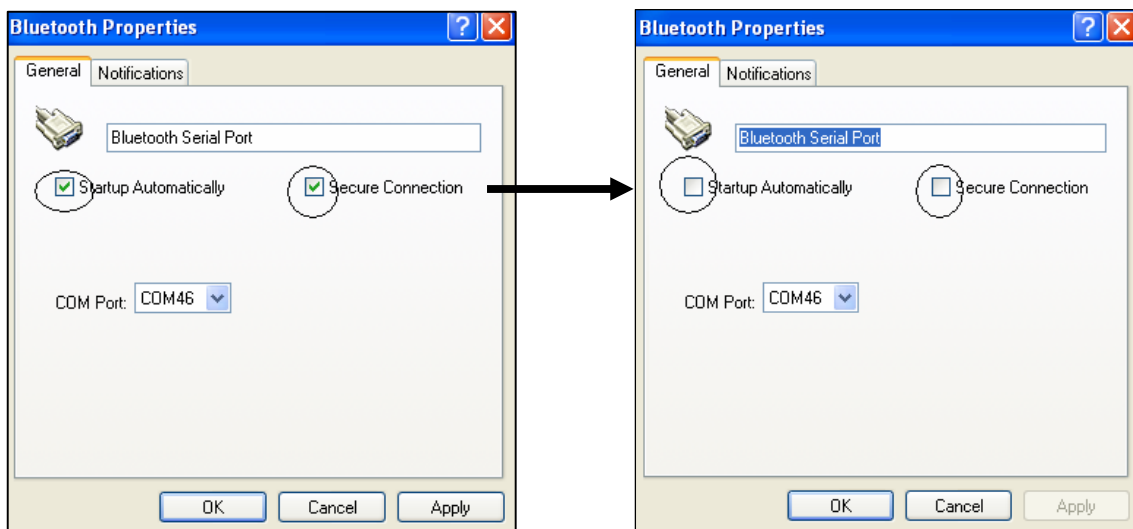
Installation

Bluetooth USB Adapter Driver Installation

35. Choose the **Local Services** tab. Select the **Bluetooth Serial Port** list item and click the **Properties...** button.



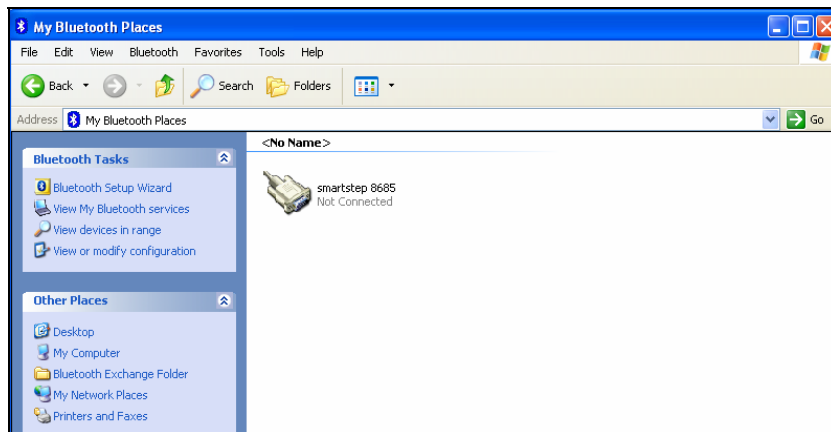
36. Uncheck the **Secure Connection** and the **Startup Automatically** checkboxes. Click **OK**.



37. Double-click the **My Bluetooth Places** icon on the desktop.



38. Double-click the icon you named in step 29.



39. The location of the serial port number that is required by the SmartStep program is marked in the screenshot. Click **OK**.






40. The icon should change to the icon shown below, the control unit beeps twice to indicate that the connection with the device has taken place .



Installation

SmartStep™ Antenna Installation Instructions

The Bluetooth icon that is located in the notification area of the taskbar can be one of the following colors:

White - The adapter is connected and enabled.	Red - The adapter is not connected to the USB port. Bluetooth support is disabled.	Green - Bluetooth communication was established.
		

3.4 SmartStep™ Antenna Installation Instructions

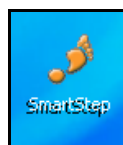
- No antenna installation is needed.
- Antenna is internal and assembly on the PCB (Printed Circuit Board)

3.5 Configure SmartStep™ for Bluetooth Usage



Make sure that the Bluetooth USB adapter is placed at a location free from signal obstruction. Concrete walls, metal substances, paints with metal composites, etc. may cause signal obstruction and disable the Bluetooth function.

1. Start the SmartStep™ software, by double-clicking on the desktop shortcut icon



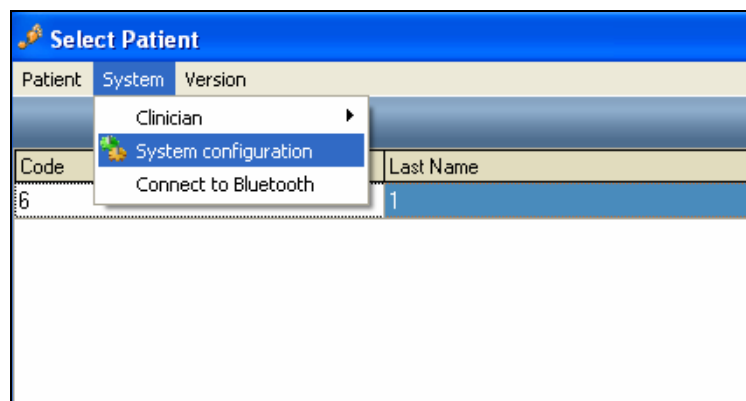
Or by clicking on the SmartStep shortcut in the Start->Program Files->SmartStep program group.



2. The Login dialog box opens.



3. Select your **User Name** from the drop-down menu and type your **Password** in the edit box.
4. Click the **OK** button to log in.
5. In the **Select Patient** window, go to the **System** menu and select **System Configuration**.



6. In the **Configuration** window select the correct Bluetooth port number and click **OK**. See step 39 of the Bluetooth USB adapter Installation section.

