PHILIPS

ST80i Stress Test System

Instructions for Use

ST80i Stress Test System

INSTRUCTIONS FOR USE

Edition 1
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Notices

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Edition History

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Applicable to ST80i, version A01.00 and later.

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Warranty

Philips Medical Systems reserves the right to make changes to both this *Instructions for Use* and to the product that it describes. Product specifications are subject to change without notice.

Nothing contained within this *Instructions for Use* is intended as any offer, warranty, promise, or contractual condition, and must not be taken as such.

Responsibility of Manufacturer

Philips Medical Systems only considers itself responsible for any effects on safety, reliability, and performance of the StressVue system if:

– assembly operations, extensions, re-adjustments, modifications or repairs are done by persons authorized by Philips Medical Systems, and

– the electrical installation of the relevant room or vehicle complies with the IEC or national requirements, and

– the instrument is used according to the instructions for use presented in this manual.

Authorized EU-representative

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European Directives

This product consists of hardware and software. The hardware carries the CE mark based on the declarations provided in the User's Guide for the IT hardware.

The ST80i software, the wireless patient module, and the Philips thermal printer are class IIa medical devices under the Medical Device Directive 93/42/EEC and carry the CE 0123 mark accordingly.

CAUTION

THIS PRODUCT IS NOT INTENDED FOR HOME USE. IN THE U.S., FEDERAL LAW RESTRICTS THIS DEVICE TO SALE ON OR BY THE ORDER OF A PHYSICIAN.

Responsibility of Customer

The user of this product is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Global Medical Device Nomenclature (GMDN)

The 5-digit GMDN code adjacent to the symbol is defined in the EN ISO 15225.

GMDN **36145**

WARNINGS

As with all electronic equipment, Radio Frequency (RF) interference between the ST80i system and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, should be evaluated carefully and any limitations noted before the equipment is placed in service.

Radio frequency generation from electrosurgical equipment and close proximity transmitters may seriously degrade performance. Philips Medical Systems assumes no liability for failure resulting from RF interference between Philips Medical Systems medical electronics and any radio frequency generating equipment at levels exceeding those established by applicable standards.

Use of accessories other than those recommended by Philips Medical Systems may compromise product performance.

Trademarks

Windows is a registered trademark of Microsoft Corporation.

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Safety Summary

This chapter provides important safety information related to the use of the ST80i Stress Test System.

US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Conventions Used in the *Instructions for Use*

The following conventions are used in the *ST80i Stress Test System Instructions for Use*, this guide.

WARNING **Warning statements describe conditions or actions that may result in personal injury or loss of life.**

CAUTION Caution statements describe conditions or actions that may result in damage to equipment or software.

NOTE Notes contain additional important information about a topic.

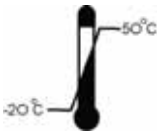
Refer to the manual(s) accompanying the ST80i Stress Test System that pertain to the system's computer hardware for additional definitions of symbols that may be present.

Symbols Marked on the ST80i System

Symbol	Description
	Attention. See the *ST80i Instructions for Use* and other product documentation for information. For information about the Advanced Interface Module, see "Important Notes about the Advanced Interface Module" on page x.
	ECG physio isolation is type CF, defibrillator proof. Suitable for all patient applications including direct cardiac application. System is in continuous operation.

Symbol	Description
	Indicates that the system is receiving alternating currents.
	Fuse
	The connector near this symbol receives an incoming signal.
	CE mark.
	The number next to this symbol is the serial number of the system.
	The number next to this symbol is the product model number of the system.
	Dispose of in accordance with the requirements of your country.
IPX0	An International Protection Rating of “IPX0” indicates that the equipment has no special protection against moisture ingress. The ST80i System carries this rating.
IPX4	An International Protection Rating of “IPX4” indicates that the equipment is protected against slashing water from any angle. The Wireless Patient Interface Module carries this rating.
	Canadian Standards Association (CSA) Certification Mark. Indicates that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.

Symbols Marked on the ST80i System Packaging

Symbol	Description
	Keep dry.
	Keep out of direct sunlight.
	Acceptable temperature range.
	Move and store packaging this end up.
	Fragile.
	Recycle the packaging materials after use.
	Manufacturer

Disposal Information

This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws. (Within this system the backlight lamps in the monitor display may contain mercury.)

Remove all batteries prior to disposing of any system components. Properly dispose of or recycle depleted batteries according to local regulations. Then dispose of the device in accordance with local, state, or federal regulations for equipment containing electronic parts.

Important Patient and Safety Information

Patient and safety information is divided into several sections:

- ST80i Stress Test System (next section)
- Medical isolation transformer (page ix)
- Philips advanced interface module (AIM) (page x)
- Philips wireless patient interface module (PIM) (page xi)

For information about electromagnetic compatibility (EMC) with surrounding devices, see “Electromagnetic Compatibility (EMC) - To be finalized” on page E-7 of Appendix E, “Specifications and Requirements”

Safety Information for the ST80i Stress Test System

The Philips ST80i Stress Test System, when operated with the ST80i AIM, AIM data cable, ST80i PIM, and lead wires, shall meet all of the EMC requirements specified in the following standards:

- IEC 60601-1:1988 + A1:1991 + A2:1995 Medical Electrical Equipment – Part 1 - General requirements for basic safety and performance
- AAMI EC11:8/2007 - Diagnostic Electrocardiographic Devices
- IEC 60601-2-25:1993 + A1:1999 - Particular requirements for the safety of electrocardiographs
- AAMI EC53:12/2008 - ECG cables and leadwires

Warning Statements for the ST80i System

WARNING **Failure to follow these warnings could affect both patient and operator safety.**

- Do not use the ST80i System in the presence of flammable vapors.
- Do not use the ST80i System in the presence of explosive gases. AC power connection/ disconnection or electrostatic discharge (ESD) may result in spark occurring in an environment where explosive gases are used.
- Submersion and/or conditions that subject the ST80i System to liquid ingress create a shock hazard.
- When operating the ST80i System, ensure that the system and all other electrical equipment connected to or near the patient are effectively grounded.
- Do not touch accessible connector pins and the patient simultaneously.
- The ST80i System has been safety tested with the recommended accessories, peripherals, and leads, and no hazard was found when the system is operated with cardiac pacemakers or other stimulators.

- To maintain designed operator and patient safety when assembling a medical electrical system for use in the patient environment, the responsible organization shall ensure that peripheral equipment and accessories used that can come in direct patient contact must comply with the following standards:
  - IEC 60601-1-1:2000 aka CAN/CSA-C22.2 No.60601-1-1:02
  - EN 60601-1-2:2001 (all parts and particularly clause 19), titled, “Medical electrical equipment - Part 1-1: General requirements for safety - Collateral Standard: Safety requirements for medical electrical systems”
  - EN 60601-1:2006 (clause 16 and particularly clause 16.6), titled, “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”
- Connecting multiple medical electrical instruments to the same patient may pose a safety hazard due to the summation of leakage currents. Any combination of medical electrical instruments should be evaluated by local safety personnel before being put into service. For equipment not certified to medical electrical equipment standards that may be used within the patient vicinity, an appropriately rated isolation transformer is required.
- Do not connect to the system any items which are not specified as part of the system.
- The PC, LCD, thermal printer, and desk light, purchased as part of a complete system must be plugged into the medical-grade isolation transformer provided with ST80i.
- Plug all accessories used with ST80i into the medical-grade isolation transformer provided as part of the “software-only” solution.
- Do not connect additional Multiple Portable Socket-Outlets (MPSOs) or extension cords to the system.
- The ST80i USB and RS-232 ports should be connected only to treadmills, ergometers, and NIBP monitors that are certified to meet IEC 60601-1 and are listed as supported devices in the Instructions for Use. See See “Supported Treadmills and Ergometers” on page 7. of Appendix E, “Specifications and Requirements”.
- The performance and safety of the ST80i System cannot be guaranteed if you use non-compatible accessories.
- Only computers, monitors, and printers approved by a National Certification Body (NCB) or a Nationally Recognized Testing Laboratory (NRTL) to IEC 60950-1 shall be connected to the ST80i system. All computer, monitor and printer outputs shall comply with IEC 60950-1 limited power source requirements.
- The use of ST80i with equipment (electrosurgical equipment and some respiration transducers) that applies high frequency voltage to a patient is not supported and may produce undesired outputs.
- To prevent burns to the patient, remove all ECG electrodes and lead wires prior to the use of high frequency surgical equipment (including electrosurgical equipment and some respiration transducers).
- Only install Philips software on the ST80i System. The installation or use of software, security patches, or updates not approved by Philips is strictly prohibited and system safety and performance are not guaranteed.

- Use only shielded LAN cable when connecting the cable to the ST80i LAN port.
- Use Philips-approved lead wires with defibrillator protection resistors.
- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with the wireless PIM or lead wires. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
- Do not contact floating electrodes during defibrillation, and avoid touching the lead wires or conductive surfaces on the trolley during defibrillation.
- Conductive parts of the patient lead wires, electrodes, and associated Type CF connections, should not come into contact with other conductive parts, including earth ground.
- Electrodes of dissimilar metals should not be used.
- Check lead wires, the cable between the PC and the treadmill, the cable between the PC and the NIBP module, the AC adapter, and power cords daily for any worn or cracked insulation to ensure that no inner conductive material is exposed. Discard worn accessories and replace them only with Philips accessories.
- The ST80i System should only use grounded power cords (three-wire power cords with grounded plugs) and connect to grounded electrical outlets that are labeled as “Hospital Only” or “Hospital Grade.” **Never** adapt a grounded plug to fit an ungrounded outlet by removing the ground prong.
- EMI generated by the ST80i System may cause nearby equipment to fail.
- Short-range radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, and DECT phones. Outside the frequency band and 5% above and below, i.e. the exclusion band according to IEC 60601-1-2, the short-range radio connection is immune up to 3V/m in the frequency range from 80 MHz to 2.5 GHz. Depending on the strength and duration of the interference, the interruption may occur for an extended period. Any interruption of the signal due to interference, moving out of range, or for other reasons is indicated via an RF signal status indicator on both the PIM as well as on the main screen.
- If your system includes the trolley, ensure that components are installed securely and that no items are placed on the trolley that could cause the trolley to become unstable.
- The maximum weight to be placed on the optional shelf for a laser printer is 45 pounds.
- If your system includes the trolley, always lock the wheel brake when the trolley is not in motion. Press down on the brake tab to set the brake and lift up on the tab to release the brake.
- Safe removal of the all-in-one display from the trolley requires two people.
- Placing or spilling liquids on the trolley may cause electrical safety hazards and/or system malfunction.
- Allow the patient to move freely by:

  - taking care when dressing the ECG cables so as to minimize the potential tripping hazard during the stress ECG study process
  - securing the patient lead set, power cable, treadmill cable, echo cable, NIBP cable, and SpO2 cable away from patient's feet before beginning exercise stage
- The ST80i captures and presents data reflecting a patient's physiological condition that, when reviewed by a trained physician or clinician, can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis.
- Both analog ECG output and TTL sync output are not in real time: there is a delay between the patient's physiological activity and the appearance of its representative signal at the external port. This signal should not be used for analysis.
- To get the most accurate interpretation during resting ECG, use traditional limb lead placement.
- For the user's convenience only, rhythm change notifications are provided when specific rhythm changes are detected; however, it is the responsibility of the trained healthcare professional to determine the type of rhythm change and take appropriate action. Additionally, the healthcare professional should not assume that all rhythm changes will be detected, and they are responsible for taking action when rhythm changes are observed on the displayed waveforms and the system fails to provide a notification. It is expected that only properly trained healthcare professionals working directly under the supervision of a qualified physician will be operating the ST80i System during testing.
- ST80i cannot import ECGs from another vendor's stress system.
- "Simulated ECG" mode must be turned off when testing patients.
- If the "Stop Treadmill" GUI button does not respond for any reason, immediately press the red "Emergency" button on the treadmill handrail.
- The interpretive algorithm has been validated only with "standard" lead placement.
- If the patient data is found to be incorrect, you may edit the ECG file and can print a new report.
- Entering incorrect NIBP data can cause errors for NIBP-related parameters in reports.

Caution Statements for the ST80i System

CAUTION Caution statements describe conditions or actions that may result in damage to equipment or software.

- The Multiple Portable Socket-Outlet (MPSO) provided with the system shall only be used for powering equipment which forms part of the system.
- Do not pull or stretch patient lead wires as this could result in mechanical and/or electrical failures. Store patient lead wires after forming them into a loose loop.

- Do not attempt to clean the device or patient lead wires by submersion, autoclaving, or steam cleaning.
- Wipe the exterior surface of the device and patient lead wires with a compatible non-alcohol sterilizing disinfectant, then dry with a clean cloth. See “Cleaning the ST80i System” on page 5-2 in the “Maintaining the ST80i System” chapter for a list of approved disenfectants.
- Be careful not to damage the display when moving the trolley or when moving other equipment near trolley.
- To prevent possible damage to the device during transport and storage (while in original packaging), the following environmental conditions must be adhered to:

  Storage Temperature Range:

  -20°C to 50°C (-4°F to 122°F)

  Storage Humidity Range:

  10% to 90% (non-condensing)

  Storage Pressure (altitude):

  Up to 4,572 m (15,000 ft.) altitude
- Allow the device to stabilize within its intended operating environment for a minimum of two hours prior to use. The allowable operating environment is as follows:

  Operating Temperature Range:

  10°C to 40°C (50°F to 104°F)

  Operating Humidity Range:

  10% to 90% (non-condensing)

  Operating Pressure (altitude):

  0 to 3,048 m (10,000 ft) altitude (697 mbar)

Important Notes about the ST80i System

- ST80i may become inoperative when the front-end (PIM) signal acquisition is interrupted due to low PIM battery power, loss of wireless communication between the PIM and the receiver (AIM), and/or loss of USB communication between the AIM and the host PC. ST80i displays a lead-off condition for all leads when signal acquisition is lost and absence of signal strength bars when wireless communication is lost. These inoperative conditions will be saved and indicated on printed reports.
- Power off the system and remove the input AC power cord before installing, repairing, or servicing any hardware.
- Proper patient preparation is important for proper application of ECG electrodes and operation of the device. Use medical tape to fix the lead wires to the chest in order to help minimize the strain applied to the electrode connections, thus reducing noise and the possibility of a leads-off condition.
- ST80i automatically prevents connection to a LAN or WLAN while the system is connected to a patient study.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:

  - Class I equipment
  - Type CF applied parts
  - Ordinary equipment
  - Not suitable for use in the presence of flammable anesthetics
  - Continuous operation
- Philips will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.
- Because of its sampling characteristics and the asynchronism between sample rate and signal rate, ST80i may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings.
- ST80i can download ECGs via the TraceMasterVue server for review.

Safety Information for the Medical Isolation Transformer

Warning Statements about the Medical Isolation Transformer

WARNING **Failure to follow these warnings could affect both patient and operator safety.**

- Use of this transformer with equipment other than originally supplied, or surpassing the ratings, may cause damage, fire, or injury.
- When using additional peripheral equipment powered from an electrical source other than the isolation transformer, the combination is considered to be a medical system. It is the responsibility of the operator to comply with IEC 60601-1-1 and test the medical system according to the requirements. For additional information, contact Philips.
- All components (whether supplied by Philips or purchased from another source) attached to the ST80i PC, including the PC, printer, monitor, and optional blood pressure monitor, must be plugged into a medical isolation transformer to ensure the system is properly grounded. However, do not plug a laser printer into the isolation transformer provided with ST80i. Power for the laser printer must be provided from another source that complies with your facility's safety requirements or IEC 60601-1.

Caution Statements about the Medical Isolation Transformer

CAUTION Caution statements describe conditions or actions that may result in damage to equipment or software.

- Before connecting your equipment to the isolation transformer, make sure the voltage selector (located above the power cord) matches the line voltage.

Important Notes about the Medical Isolation Transformer

- Do not connect the treadmill or the ergometer to the medical isolation transformer supplied by Philips. It is important that the treadmill and ergometer has its own source of unshared power to avoid an interruption to the power supply to the ST80i System. The treadmill and ergometer should have its own circuit and fuse/breaker in a local power distribution box.

Safety Information for the Advanced Interface Module

Warning Statements about the Advanced Interface Module

WARNING **Failure to follow these warnings could affect both patient and operator safety.**

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

Caution Statements for the Advanced Interface Module

CAUTION Failure to heed these caution statements may result in damage to equipment or software.

- The advanced interface module complies with FCC radiation exposure limits set forth for an uncontrolled environment.

Important Notes about the Advanced Interface Module

- Use Conditions: This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:
  - This device may not cause harmful interference
  - This device must accept any interference received, including interference that may cause undesired operation
- The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.
- FCC Note: This device has been tested and found to comply with the limits for a Class B digital device pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This 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 radio communications.

  However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can

be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the device and receiver
- Connect the device into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/television technician for help

- The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). Class 1 radio equipment. Member states may apply restrictions on putting this device into service or placing it on the market.
- Industry Canada Statement:

  This device complies with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

  - This device may not cause harmful interference, and
  - This device must accept any interference received, including interference that may cause undesired operation.

  Ce dispositif est conforme à la norme CNR-210 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes:

  - Le dispositif ne doit pas produire de brouillage préjudiciable, et
  - Ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.
- This Class B digital apparatus complies with Canadian ICES-003.

  Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.
- The AIM’s LED blinks every two seconds when the AIM is functioning properly. If the AIM LED does not blink, the AIM is not functioning properly.
- The 5-pin connector port on the back of the AIM is non-functional.
- Do not connect TC series cardiograph patient interface modules to the 5-pin connector port on the back of the AIM.

Safety Information for the Wireless Patient Interface Module

For information about electromagnetic compatibility (EMC) with surrounding devices, see “Electromagnetic Compatibility (EMC) - To be finalized” on page E-7 of Appendix E, “Specifications and Requirements”.

Warnings about the Wireless Patient Interface Module

WARNING **Failure to follow these warnings could affect both patient and operator safety.**

- The wireless patient interface module transmits data reflecting a patient's physiological condition to a properly equipped system and when reviewed by a trained physician or clinician can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis.
- To maintain designed operator and patient safety when assembling a medical electrical system for use in the patient environment, the responsible organization shall ensure that peripheral equipment and accessories used that can come in direct patient contact must comply with the following standards:
  - IEC 60601-1-1:2000 aka CAN/CSA-C22.2 No.60601-1-1:02
  - EN 60601-1-2:2001 (all parts and particularly clause 19), titled, "Medical electrical equipment - Part 1-1: General requirements for safety - Collateral Standard: Safety requirements for medical electrical systems"
  - EN 60601-1:2006 (clause 16 and particularly clause 16.6), titled, "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"

  Any combination of medical electrical instruments should be evaluated by local safety personnel before being put into service. For equipment not certified to medical electrical equipment standards that may be used within the patient vicinity, an appropriately rated isolation transformer is required.
- FCC Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device or lead sets. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
- Defibrillation protection is guaranteed only if the original lead set is used.
- Ensure that the electrodes or lead wires do not come in contact with any other conductive materials (including earth-grounded materials), especially when connecting or disconnecting electrodes to or from a patient.
- If your facility is using more than one PIM, each one must be added to the ST80i application under Settings (System Settings; I/O Devices). When you connect the patient to one of the PIM devices, you also need to verify the address on the device with the address that shows up on the Pre Exercise screen.
- A possible explosion hazard exists. Do not use the device in the presence of flammable anesthetics, or flammable mixtures with air, oxygen, or nitrous oxide.
- Some stimulators may cause interference with the signal.

Caution Statements for the Wireless Patient Interface Module

CAUTION Failure to heed these caution statements may result in damage to equipment or software.

- The wireless patient interface module complies with FCC radiation exposure limits set forth for an uncontrolled environment.
- The wireless PIM supports 1.5V AA alkaline batteries only. Replace the battery if the low-battery alert appears before the stress test starts.
- The wireless PIM uses an off-the-shelf disposable AA alkaline battery for power. If you use an off-the-shelf rechargeable AA battery, the remaining capacity indication may be inaccurate.
- Minimum operating time of the wireless PIM with new, fully charged batteries: 6 tests per day, 30 minutes average per test, for 5 days. Performance may vary according to brand of batteries used.
- If you use off-the-shelf rechargeable batteries, then you must also provide a compatible battery recharging unit independent of the ST80i System. To ensure safe use and adequate maintenance of rechargeable batteries, follow the battery manufacturer's instructions for use.
- Other than the replaceable battery, there are no user-serviceable parts inside. Any modification of this device may alter defibrillator protection. Any modification to any part of this device is to be performed by qualified service personnel only.
- Follow the correct procedure to select the wireless PIM when multiple modules are detected. See "Select the PIM" on page 3-13 of the "The Patient Session" chapter.
- To prevent possible damage to the keypad, do not use sharp or hard objects to depress keys; only use fingertips.
- The wireless PIM and patient lead set should be cleaned between each use.
- Do not attempt to clean the wireless PIM or patient lead set by submersion, autoclaving, or steam cleaning. Wipe the exterior surface of the device and patient cables with a non-alcohol sterilizing disinfectant, then dry with a clean cloth. See "Cleaning the ST80i System" on page 5-2 in the "Maintaining the ST80i System" chapter for a list of approved disenfectants.
- Conductive parts of the patient lead sets, electrodes, and associated Type CF connections, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.
- Do not pull or stretch patient lead sets as this could result in mechanical and/or electrical failures. Store lead sets after forming them into a loose loop.
- The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.

Important Notes about the Wireless Patient Interface Module

- Wireless patient interface module leakage currents are 100% safety tested in production.
- Use Conditions: This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:
  - This device may not cause harmful interference
  - This device must accept any interference received, including interference that may cause undesired operation
- The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.
- FCC Note: This device has been tested and found to comply with the limits for a Class B digital device pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This 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 radio communications.

  However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna
  - Increase the separation between the device and receiver
  - Connect the device into an outlet on a circuit different from that to which the receiver is connected
  - Consult the dealer or an experienced radio/television technician for help
- The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). Class 1 radio equipment. Member states may apply restrictions on putting this device into service or placing it on the market.
- Industry Canada Statement:

  This device complies with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:
  - This device may not cause harmful interference, and
  - This device must accept any interference received, including interference that may cause undesired operation.

  Ce dispositif est conforme à la norme CNR-210 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes:
  - Le dispositif ne doit pas produire de brouillage préjudiciable, et

  - Ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

- This ISM device complies with Canadian ICES-001.

  Cet appareil ISM est conforme à la norme NMB-001 du Canada.

- Proper patient preparation is important for proper application of ECG electrodes and operation of the device.
- Use wireless PIM belts and NIBP cuffs appropriate for the patient's size.
- Patient lead sets should be checked for cracks or breakage in its exterior properties prior to use.
- The wireless PIM includes LEDs that indicate battery power level, wireless signal quality, and lead contact status. When the wireless PIM is powered on, the battery power level LED is lit. You can click the power button anytime to check the status of the battery, wireless signal, or lead contacts.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Internally powered
  - Type CF applied parts
  - Ordinary equipment
  - Not suitable for use in the presence of flammable anesthetics or flammable mixtures of air, oxygen, or nitrous oxide
  - Continuous operation

Security Recommendations

As more patient health information is collected, stored, and transmitted electronically, on a global basis, the concern for patient privacy grows. We consider the security and confidentiality of patient data to be of paramount importance. We adhere to the highest professional standards focused on providing you with resources aimed at your regulatory compliance needs and allowing you to fully manage the safety, effectiveness, and security risks of medical devices, including your ST80i System.

Protecting Personal Information

It is essential that policies and procedures for the proper handling of personal or sensitive data, consider the confidentiality, integrity, and the availability of these types of data. Each organization using this product must provide the protective means necessary to safeguard personal information consistent with each country law, code and regulation, and consistent with the company policies for managing this information. While handling personal information is outside the scope of this document; in general, each organization is responsible for identifying:

- who has access to personal data and under what conditions an individual has authorization to use that data
- how the data is stored and the conditions by which it is stored
- how the data is transmitted and the conditions under which that data is transmitted.

The US Department of Veterans Affairs has developed a widely used Medical Device Isolation Architecture to minimize the risk of a security breach when medical devices are connected to information networks. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

Additional security and privacy information can be found on the Philips product security website at: http://www.healthcare.philips.com/main/productsecurity/.

About HIPAA Rules

If applicable, your facility's security strategy should include the standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the United States Department of Health and Human Services. You should consider both the security and the privacy rules and the HITECH Act when designing policies and procedures. For more information, please visit:http://www.hhs.gov/ocr/privacy/.

Security Controls and Safety Measures

The following controls and safety measures may further strengthen the security and confidentiality of your patient records and system in general:

- Install ST80i in a secure location and use a privacy filter on the ST80i System monitor that shields the visibility of the screen contents from angled viewing.
- In case of a power supply disruption, backup options should be handled by an appropriate power failover system.

- Implement “best practices” Windows security measures to minimize unauthorized system access. These measures include making passwords complex, regular changing of passwords, short screen saver intervals, short auto logout intervals when the system is idle, and training your users to lock the desktop when they leave the computer.
- Install McAfee anti-virus software.
- Apply Windows-recommended network security and user privilege policies to prevent:
  - the installation of any software other than Philips-approved software intended for installation on ST80i
  - the transmission of viruses via removable storage devices (e.g., USB sticks)
- Do not load or download to the computer any software, security patches, or updates not authorized by Philips. Unathorized software may compromise the operation of the system and is strictly prohibited.
- Remember that the ST80i System contains confidential patient health information (PHI) that should be safeguarded. Avoid copying patient health information to removable media. If you do, maintain physical security of the media at all times. Deleting data from rewritable/erasable media does not make the data inaccessible to a determined individual. Dispose of removable media containing patient health information in accordance with your institution’s policies.
- Upon returning the equipment to Philips, eliminate all patient health information or other confidential data, unless otherwise directed by Philips for problem investigation. Retain only the information necessary for the investigation with full agreement from both parties.
- Configure the system to not run executables (.exe files) automatically when connecting external drives. See the *ST80i Installation and Configuration Guide* for more information.
- Shut down remote desktop services as a best practice.
- Rename the built-in Windows Administrator account.
- Disable the Guest account. Every user should have his or her own identity.
- Set up a BIOS password to prevent unauthorized access to the computer setting.
- Although security safeguards to protect the system against the intrusion of malware (viruses, trojans, worms, and so on) are recommended, a possibility remains that a system can become infected. In all circumstances, the system safety mechanisms are designed to remain intact, even when you might notice unfamiliar system behavior and performance. If this happens repeatedly, such as after the system has been switched off and on again, contact Philips customer support to have the system checked and, if needed, cleansed of malware.
- Malware prevention software should be configured to receive automatic updates. If the virus scanning software has detected infection by malware, do not use automatic repair utilities because the integrity of the repaired software cannot be guaranteed. Contact Philips service to assess and repair the system. Additionally, please be sure to adhere to local procedures regarding malware infection, which may include disconnecting from the network until the situation is resolved.

- Perform regular backups of system data and store in a secure location. ST80i allows you to back up the stored ECG report and the configuration setting. Users with adminstrator accounts can backup and restore ECG reports from the “Archive” screen; administrators can also backup the configuration setting on the “Settings” screen.
- The exported configuration setting can be imported on the “Settings” screen to restore the ST80i software.
- User must maintain physical security of the media that stores the backup files at all times.
- You risk losing ePHI if you transfer it to unsupported and/or obsolete backup media (e.g., floppy disks).
- Limit Web browsing to the downloading of Philips-authorized security patches or updates. Web as browsing dramatically increases the chance of the system being infected by malicious software.
- ST80i is not generally used in situations where emergency access is required. If this is important to your organization, it is recommended that you establish administrative procedures to permit emergency access to the device when normal logon and authentication credentials are not available.
- Visit the Philips security website at http://www.healthcare.philips.com/main/productsecurity/ for the latest security updates from Philips.

The Philips ST80i Stress Test System

Intended Use

The Philips ST80i Stress Test System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data, creates summary tables, trends, and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the Stress system is intended to be reviewed, confirmed, and used for diagnostic purposes by trained medical personnel to assist in the diagnosis of CAD and the patient's physiological condition during stress exercise testing. The arrhythmia detection portion of the ST80i Stress Test System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

Indications for Use

The Philips ST80i Stress Test System is indicated for use in exercise ECG testing where the clinician decides to evaluate the electrocardiogram of patients at 10 years or older, as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment, or to rule out causes for symptoms of CAD. The Philips ST80i Stress Test System is not intended to be used as a physiological monitor.

The CAlg-STR Exercise ECG Analysis Algorithm

Intended Use

The intended use of the CAlg-STR Exercise ECG analysis algorithm is to analyze multi-channel ECG waveforms acquired from a patient and produce measurements such as heart rate, detect ventricular arrhythmias, form representative beats, and calculate ST segment deviation (elevation or depression) and ST slope for review by a trained physician or clinician in determining a diagnosis. The measurements should not be used as a sole means for determining a patient’s diagnosis.

Indications for Use

The analysis algorithm is indicated for use in those situations where the clinician decides to evaluate the electrocardiogram of patients at 10 years old and older, as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms. The analysis algorithm is not intended to be used as a physiological monitor.

1

About the Philips ST80i Stress Test System

The Philips ST80i Stress Test System is a PC-based diagnostic tool for use in the exercise stress testing laboratory. Electrocardiographic data obtained during stress testing is acquired, processed, recorded, analyzed, archived, and exported. The ST80i software creates summary tables, identifies trends, and generates a final statistical report, which trained clinicians review to assist in the diagnosis of the patient's condition.

The ST80i System interfaces to, and controls, a compatible treadmill or ergometer and non-invasive blood pressure monitor. It can also be used with the pharmacological form of testing. The TTL and analog output options allow a selectable ECG signal to be sent to an Echo system for further tests.

This chapter provides the following information:

Overview

The ST80i System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data, creates summary tables, trends, and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the stress system is intended to be reviewed, confirmed and used for diagnostic purposes by trained medical personnel to assist in the diagnosis of coronary artery disease (CAD) and the patient's physiological condition during stress exercise testing.

NOTE The arrhythmia detection portion of ST80i is provided for the convenience of automatic documentation. ST80i does not offer a diagnostic opinion; rather, it provides a high-fidelity instrument recording ECG waveforms during exercise, for the purpose of providing a tool to expedite the documentation of a test for which a clinician renders his/her own medical opinion.

ST80i provides the standard 12-lead ECG by the use of the 10-lead electrode wireless patient interface module (PIM).

Key features provided by ST80i include the following:

- Continuous ECG acquisition and analysis (ST level, risk scoring & alerts)
- Heart rate, blood pressure & SpO_2 monitoring, display and trending
- Intuitive user interface – no user training required
- Comprehensive test protocol support
- Comprehensive and customizable reports
- Comprehensive connectivity (EMR/HIS, TMVue)
- Customizable display layout
- Wireless patient connection
- Support for exercise, pharmacological, and nuclear stress testing
- Interface to ADT For patient registration
- Remote access to reports

ST80i is also programmable, allowing you to customize the operational conditions to suit your needs. You can customize:

- Up to 100 different user profiles to meet the needs of individual physicians
- Up to 100 different exercise protocols
- Automatic 12-lead ECGs
- Multiple final report formats

ST80i runs on a PC with the Windows 7 operating system. You control its functions using the keyboard and mouse or touch screen.

ST80i interfaces with a treadmill, ergometer, or as part of a pharmacological study, and captures four phases of a patient exercise test:

- Pre-exercise
- Exercise
- Recovery (and Post-Recovery)
- Report

About ST80i Documentation

Philips provides detailed instructional and reference materials to help you get the most out of your ST80i System.

Available Documentation

The following documentation is available with the ST80i system:

Getting Started Sheet	Introduces the product, lists the contents, and directs the user to the installation materials and documentation.
ST80i Installation and Configuration Guide	Describes how to set up the ST80i System, including hardware and software. Also describes how to set up the trolley and how to perform initial configuration of the software.
ST80i Instructions for Use (IFU)	Provides detailed information about ST80i functionality. It describes the operation of the product and includes all regulatory-required labeling. This guide also includes troubleshooting and maintenance information. The IFU is written for clinical professionals. They are expected to have a working knowledge of medical procedures and medical terminology as required for monitoring potential cardiac patients.
Wireless Patient Interface Module Instructions for Use	Provides information about how to set up the Philips wireless patient module and also includes all regulatory-required labeling. Includes a troubleshootingchapter and a service/maintenance chapter.
C-Alg STR Physician's Guide	Describes the ECG analysis program available on the ST80i System, and the available report formats. Includes a high-level description of the criteria logic.
ST80i Service Manual	Provides guidelines for repair on specific parts as well as information for how to order replacement parts.

Conventions Used in this Guide

The documentation and training materials for ST80i use the following typographic conventions.

Item	How Displayed
Menu item **Button name**	Menu items and button names appear in a bold no-serif font. *Example:* Click **Settings**.
Field names and list items	Field names and list items appear in a no-serif font. Example: Select the appropriate format from the Format dropdown list.

WARNING **Warning statements describe conditions or actions that may result in injury to the patient.**

CAUTION Caution statements describe conditions or actions that may result in damage to equipment or software.

NOTE Notes provide additional important information about a topic.

How to Use this Guide

This guide is intended to help you use ST80i. It also provides maintenance and troubleshooting information, as well as product specifications.

This guide is organized as follows:

Safety Summary. Lists the warnings, caution statements, and important notes that apply to using the ST80i system, the patient modules, and the isolation transformer. Read this chapter before operating any of the equipment.

1 **About the Philips ST80i Stress Test System.** Provides a high-level overview of the ST80i System.

2 **Philips ST80i Stress Test System Overview.** Provides a general overview of the ST80i graphical user interface, features, and functionality. It also provides basic information about changing specific default settings during a Patient Session.

3 **The Patient Session.** Describes all aspects of the patient session, from getting started through the four phases of the test.

4 **Working with Reports.** Describes how to configure, view, edit, save, and print the final stress test report.

5 **Maintaining the Philips ST80i Stress Test System.** Describes how to clean and maintain the system.

A **Troubleshooting and Contacting the Response Center.** Describes some issues you might encounter and what to do about them. Also describes how to contact the Philips Response Center.

B **Protocol Reference.** Provides an example of the settings for each of the protocols provided with ST80i.

D **Ordering Options and Parts.** Provides a list of parts (including support parts)) and options you can order.

E **Specifications and Requirements.** Lists the product specifications.

Glossary. Defines common terms used with the ST80i System.

Getting Help Using ST80i

For detailed troubleshooting information, as well as details about contacting the Philips Response Center, see Appendix A, “Troubleshooting and Contacting the Response Center.”

2

An Overview of the ST80i Stress Test System

The ST80i Stress Test System is used for the acquisition, analysis, and presentation of stress test data during the patient session. The application also controls the peripheral devices such as the treadmill, ergometer, and blood pressure equipment.

A patient session is the period of time when the exercise stress test is performed and waveforms are acquired and processed for a single patient. Patient information is linked with all waveform data acquired during the patient session. The session starts when you begin to gather exercise data for a new exam and lasts through the generation and review of the final report.

During the patient session, you can change certain default settings as you proceed through each phase using the Toolbar icons - so that you can view or gather more specific ECG data. Other changes can be made directly on the screen as you proceed through the various stages of the exam. This may involve changing the default protocol, manually inserting a blood pressure measurement, or manually taking control of the exercise device. In addition, you can select from various print options during the patient session.

This chapter provides the following information:

User Accounts

User accounts are created with specific access privileges based on function. ST80i user accounts are categorized as follows:

- Administrators – these users are allowed to perform all operations on the system.
- Clinicians – these users are allowed to perform all operations on the system except most configuration operations. The only configuration that the Clinician would be able to perform is report configuration for fine tuning on final reporting (“Finalizing”).
- Technicians – these users are allowed to perform all operations on the system except configuration and “Finalizing.”

Only clinicians and administrators would be able to electronically sign the report.

ST80i supports at least 100 user accounts.

Starting the Application

Your user account is used to access the application. When you log into ST80i, you are logging into your preconfigured user profile.

To log in

1 Double-click the ST80i icon on your desktop. The ST80i window opens.

2 Type your User Name and Password.

3 Click **OK**.

The Main screen opens.

Figure 2-1 Main screen

The Main screen is where you perform all tasks for the application.

- To conduct a stress test, click **Patient**.
- To enter the stress system database to review and retrieve archived reports, click **Report**. In this area, you can also replay, delete, or export a selected exercise stress test.
- To review, update, or test software and firmware configurations, click **Service**.
- To hear an audio explanation of the exercise stress test, click **Explain Test**.

NOTE ST80i ships with a default audio file that explains the exercise stress test; however, you may record your own audio file and configure ST80i to play this file when the user clicks the **Explain Test** button. For more information, see the *ST80i Installation and Configuration Guide*.

- To preconfigure or change system settings, user profiles, exercise protocols and user accounts, click **Settings**.

User Profile

The system ships with a default user profile that cannot be deleted. The user profile contains preconfigured settings that are used to determine how the test will run and how the test results will be displayed, printed, saved, and exported. Some settings are fixed and cannot be changed; some settings represent a default view, which can be changed during the exercise stress test.

The preconfigured parameters of the user profile include:

- Exercise protocol and equipment
- Lead formats
- Display settings
- Report settings
- Freeze display
- Filter settings
- Algorithm settings
- Notifications
- Audio prompts

See “Using the Toolbar Icons” on page 2-15 for an explanation of the settings that can be changed during the patient session. See also “Side Panel” on page 2-11 for an explanation of the display features that are continuously updated during the patient session. On this panel you can manually override blood pressure and SpO_2, as well as equipment settings that are preconfigured as part of the user profile and/or protocol.

Refer to the *ST80i Installation and Configuration Guide* for an explanation of how user profiles are pre-configured.

Before beginning with the exercise stress test, it's important to understand the key features of the ST80i user interface along with the Toolbar icons, since you will be using them during the patient session.

ST80i Test Screen

The ST80i Test screen (user interface) provides:

- All key procedural information including the protocol being used
- Pop-ups, drill-down menus, and notes pages that can be viewed then hidden so that the leads can be viewed in their entirety
- Time of Day for correct time stamp on the start-up screen for every stress test
- Real-time ECG as well as NIBP and SpO_2, Trends, and other numeric displays that include ST values, ST slope, Double Product, and ST/HR index

On the Test screen, you have command of several functions during a patient session. You can adjust the speed and elevation of a treadmill and insert manual blood pressure data. You can also abort the exam at any point without losing any patient data. However, note that the exercise data will be lost.

Figure 2-2 ST80i Test screen

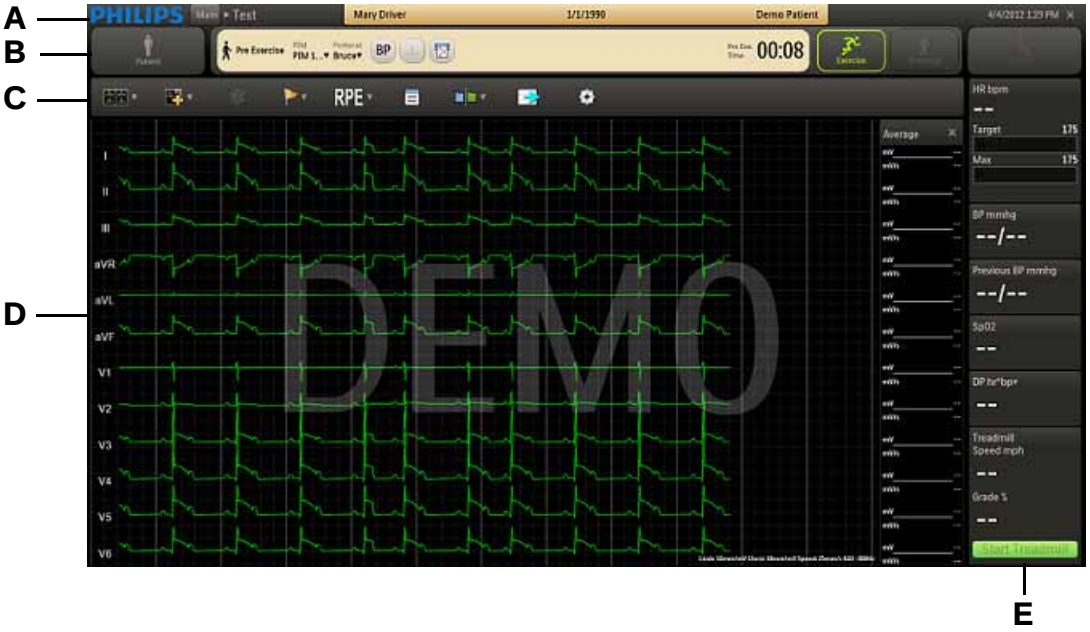


Table 2-1 ST80i Test Screen Features

Feature	Description
A	Title Bar - displays patient name date of birth and ID, along with current date and time; during the patient session, you can click the patient name in the Pre Exercise phase or Report phase to update patient information; also where the PIM battery status and RF transmitter LED indicators appear.

Feature	Description
B	Procedure Bar - used to control the exercise stress test process; shows exercise stage; selected patient interface device; protocol; **BP**, **ECG Print** and **Rhythm Print** buttons; and stage time
C	Toolbar - displays the Toolbar icons that provide quick access to frequently used commands throughout the exercise stress test
D	Waveform Screen - provides real-time ECG waveforms during the exercise stress test
E	Side Panel - provides real-time updates during the stress test as well as target heart rate, NIBP and SpO_2, and exercise equipment data (speed, grade, stop & start)

Title Bar

At any time during the Pre Exercise or Report phases of the patient session, you can use the title bar to manually input and edit patient information with data that will be centrally stored in the stress database. The Title Bar includes the features shown and described below.

Figure 2-3 TitleBar

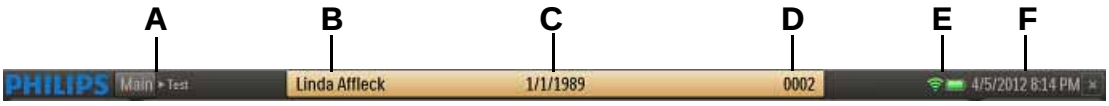


Table 2-2 Title Bar Features

Feature	Description
A	Navigation Keys [Main →Test] - Click **Main** to leave exercise test and return to Main screen
B	Patient Name - Click the patient name to update patient information and add notes on the Patient Information tab of the Patient Demographics screen
C	Patient's Date of Birth
D	Patient ID
E	LED indicators for the RF Transmitter and PIM battery status
F	Current Date and Time

To add or update patient information

1 Click on the Patient Name in the title bar.

The system displays the Patient Demographics window.

Figure 2-4 Patient Demographics window

2 Enter new information for the patient or update the fields as needed during the stress test.

3 Click **OK** when finished to save the data.

If you manually update patient information, including Notes and Symptoms during the test or on the Report screen, this information is not updated in the Patient profile in Worklist.

Procedure Bar

By default, the Procedure Bar is at the top of the screen. You can change the location of the Procedure Bar to the bottom of the screen. See the *ST80i Installation and Configuration Guide* to change the default setting [Settings → User Profile → Display].

Figure 2-5 Procedure Bar

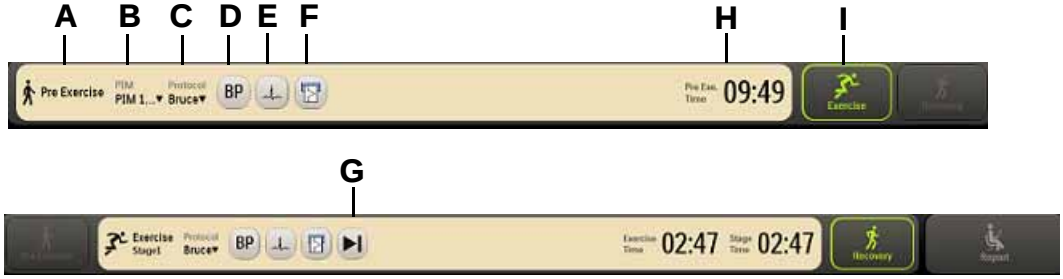


Table 2-3 Procedure Bar Features

Feature	Description
A	Current exercise phase (Pre Exercise, Exercise, Recovery, Report)
B	PIM device (only in the Pre Exercise stage)
C	Protocol (Protocol drop-down list)
D	**BP** button - used to manually command the optional automatic blood pressure (NIBP) device to take an unscheduled blood pressure measurement
E	**Print ECG** button
F	**Rhythm print** button
G	**Advance** (to the next stage) or **Stop** buttons
H	Exercise stage and time
I	Phase buttons (Pre Exercise, Exercise, Recovery, Report) - next phase is illuminated in green

Toolbar

The Toolbar contains the Toolbar icons that are used during the patient session. The icons provide quick access to frequently used commands.

During the patient session, the waveform screen is displayed. You can use the Toolbar icons during the patient session to view or hide specific exercise stress test data - which appear as an overlay on the waveform screen.

Some of the icons allow you to change specific default settings as you proceed through each phase of the patient session, while others give you a magnified view of various data in relation to the ECG.

When you mouse over each icon, a Tool Tip is displayed.

See “Using the Toolbar Icons” on page 2-15 for a complete description of the icons and their functionality.

The default setting for the Toolbar is at the top of the screen. You can change the location of the Toolbar to the bottom of the screen. See the *ST80i Installation and Configuration Guide* to change the default setting [Settings → User Profile → Display].

Waveform Screen

Real-time ECG waveforms appear on the Waveform screen. The default setting is 12-Lead.

With the customizable options of ST80i, you can use the Toolbar icons do the following:

- Change the default lead you want to view (12, 6x2, 6, 3)
- Display the magnified beat
- Display and/or print the average complexes
- Show or remove magnified beat, trends, anatomical representations and average complexes from the ECG print strip

On the bottom of the screen, the current settings appear for the following:

- Limb Lead amplitude
- Chest Lead amplitude
- Speed of trace display
- Filter – low and high pass

Figure 2-6 Limb Lead, Chest Lead, Speed, and Filter Settings

When you change these default settings using the Toolbar icons, they appear in this location.

Side Panel

The Side Panel shows a continuous display of all relevant physiological parameters as well as visual indicators for current heart rate and a dynamic change in heart rate. From the Side Panel, you can override NIBP and SpO_2 values. In addition, you can change the treadmill speed and duration during a patient session or stop the treadmill altogether.

The Side Panel provides the following:

Figure 2-7 Side Panel

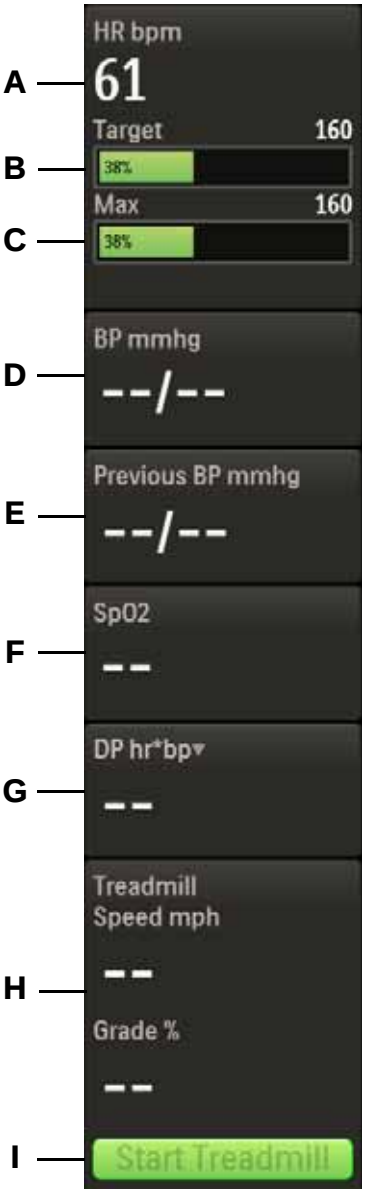


Table 2-4 Side Panel Features

Feature	Description
A	Heart rate beats per minute
B	Target heart rate – visual and audible indicators when target heart rage is achieved
C	Maximum heart rate
D	BP mmhg – current blood pressure; used also to manually insert current BP measurement
E	Previous BP mmhg – when BP is taken as pre-configured by stage, previous BP is shown; previous BP is also shown when you manually insert current BP measurement
F	SpO_2 numeric data with appropriate stage; you can manually insert SpO_2 data
G	DP hr*bp (Double-Product – default); drop-down includes: ■ METS – establishes metabolic equivalent [Algorithm calculation of HR, speed of Treadmill, etc.] ■ ST mm – ST Index
H	Treadmill speed (mph), grade %, or ergometer watts
I	Treadmill or Ergometer button (Start/Stop). The button displays “Unavailable” when the treadmill or ergometer is unavailable.

Heart Rate bpm

This field shows the current heart rate of the patient.

Target Heart Rate (130)

There are visual and audible indicators when the target heart rate is achieved.

This field shows the % of Target Heart Rate achieved.

- Target Heart Rate is X% of maximum heart rate – as established in User Profile
- Target Heart Rate % is pre-set (typically 85%)

See the information regarding Target Heart Rate in the *ST80i Installation and Configuration Guide.*

Max (220)

Shows the maximum heart rate for patient, male or female.

BP mmhg

When the patient's NIBP is collected during the exercise stress test based on the defined interval in the Exercise Protocol (Off, Begin, End, Every), the BP mmgh field displays the measurement. If you click the **BP** button during the patient session, the current blood pressure measurement also displays in this field.

With this interface, there are visual and audio prompts (if enabled) for NIBP acquisition.

To enable audio alerts, see the *ST80i Installation and Configuration Guide*.

This field is also used to manually enter a blood pressure measurement, if an NIBP monitor is not being used.

To override NIBP or manually insert the blood pressure measurement

NOTE Once the NIBP or BP is manually overwritten, ST80i no longer updates the real-time value from the NIBP monitor.

1. Click the dashed lines or current BP value in the BP mmhg field.
2. Type in the blood pressure measurement.
3. Click **OK.**

Previous BP mmhg

When the blood pressure monitor records the current blood pressure measurement, the Previous BP mmgh field displays the previous measurement. It will also display the previous blood pressure measurement when you click the **BP** button on the Procedure bar.

If you are using a blood pressure cuff, when you manually enter the blood pressure measurement, this field records the previous blood pressure measurement.

SpO_2

The patient's SpO_2 is collected in real time through a sensor. During the stress test, SpO_2 is measured automatically and is continuously displayed on the screen. With this interface, there are also visual and audio prompts (if enabled) for SpO_2 acquisition.

To enable audio alerts, see the *ST80i Installation and Configuration Guide.*

You can override the NIBP and SpO_2 values. Depending on the NIBP monitor used, you may need to manually enter the SpO_2 data.

To override or manually enter the $Sp0_2$

1. Click the dashed lines or value.
2. Type in the latest SpO_2
3. Click **OK**.

Double Product (HR*BP)

Double Product is the current heart rate times the current blood pressure measurement.

Use the drop-down arrow to change from Double Product display to the following:

- About METS
- About ST X mm (or mV) – X is the selected Zoom Lead

About METS

The METS calculation establishes a metabolic equivalent based on the Algorithm calculation of HR, speed of treadmill, etc.

About ST X mm – by Zoom Lead

You have the option to change the lead in view using the drop-down menu to view the ST Index (ST level).

To change the lead in view

1. Click the **Hide/Show View** icon.
2. Select Show Zoom ST.
3. Click the Lead drop-down arrow in the Zoom ST lead display.
4. Select the lead to view.

Treadmill Speed, Grade %

These two fields capture the treadmill speed and elevation by stage.

You can also use these fields to manually change the treadmill speed and elevation. To do this, see “Controlling the Treadmill or Ergometer” on page 3-35.

During the entire stress test, the host-side application validates the response between the treadmill (or ergometer) and the PC to ensure that the communication is successful.

Treadmill Button

The **Treadmill** button is used to stop and start the treadmill during a patient session.

WARNING The ST80i USB and RS-232 ports should be connected only to treadmills, ergometers, and NIBP monitors that are certified to meet IEC 60601-1 and are listed as supported devices in the Instructions for Use. See "Supported Treadmills and Ergometers" on page E-7 of Appendix E, "Specifications and Requirements".

CAUTION If the "Stop Treadmill" GUI button does not respond for any reason, immediately press the red "Emergency" button on the treadmill handrail.

Ergometer Button

The **Ergometer** button is used to stop and start the ergometer during a patient session.

Using the Toolbar Icons

Generally, you will not change the settings associated with a selected profile and protocol during an exercise stress test. However, there may be instances when you wish to change specific display settings. You can change display settings by using the Toolbar icons.

Figure 2-8 Toolbar Icons

When you mouse over each icon, a **Tool Tip** is displayed.

Using the **Toolbar** icons, you can do the following:

- Select what leads to view in real time
- Change the default setting of the waveforms on the waveform screen
- Display a zoomed view of an average complex to either a specified lead or for the lead that shows the most significant change in ST level
- Freeze the ECG or enable a filter to reduce noise
- Use the lead map diagram to check the lead wire contact with a predefined, color-coded indicator to show which lead is off

- Compare the current averages with reference ECG (resting, supine, hyperventilation averages) and worst case for all 12 leads. ST80i is able to select a new ECG complex or 10s strip as the new reference. This can be done on the screen and is available at any point during the test.
- Hide or show the magnified beat, trends, anatomical representations (ST Map) and average complexes that appear over the real-time waveform display
- View a two-dimensional, color-coded anatomical representation of ischemic area/ segments (ST Map); 2D real-time updates anatomical representation (ST Map) every 10 seconds
- Create events during the test with associated notes
- View trend graphs for Heart Rate, METS, BP, SpO_2, and ST values at any time
- View magnified ST and morphological changes (including ST morphology changes, T wave morphology changes, QRS morphology changes) in the various leads.

The following table provides an overview of each icon.

Table 2-5 Toolbar Icons

Icon	Description
Waveform 	The default is 12 leads; you can select from the following: ■ 12 Leads ■ 6x2 Leads ■ 6 Leads ■ 3 Leads
Hide/Show View 	Select from the following: ■ Show Lead Map ■ Show Zoom Lead ■ Show ST Map ■ Show Trend View [HR/METS; BP; ST Level] ■ Show Average Note that these settings are “sticky” – once selected they will remain until deselected.
Freeze 	Freezes the ECG in a moment in time so that you can print the event

Table 2-5 Toolbar Icons

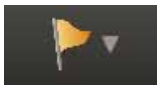
Icon	Description
Event 	Select the Event from the drop-down list and do X. The Events include: ■ Supine ■ Stand ■ Mason-Likar ■ Hyperventilation ■ Chest Pain ■ Shortness of Breath ■ Add New Event
RPE 	Rate of Perceived Exertion; from preconfigured setting
Note 	Insert comments about patient and/or test
Compare 	Compare the current zoomed ECG with a previous moment in time to compare [the delta]
Page 	Form-feed adjustment for thermal paper
RELEARN	

Table 2-5 Toolbar Icons

Icon	Description
Gear 	Quick Settings: ■ Filter (LP, HP, AC, Artifact, Smart) ■ Display (Limb Gain, Chest Gain, Speed) ■ Rhythm Print (Leads, Limb Gain, Chest Gain, Speed) ■ Sync Out (Analog Out 1 – Amplify Ratio; Analog Out 2 – Amplify Ratio; TTL Out – Polarity, Duration)

Waveform

Real-time ECG analysis employs the latest C-Alg analysis to calculate an adult patient's ECG for ST segment (elevation or depression) and to produce events and notifications simultaneously for all supported ECG leads.

The real-time waveform default is the 12-Lead. You can choose from four display formats for the real-time ECG:

- 12 Leads
- 6 x 2 Leads
- 6 Leads
- 3 Leads

To change the real-time ECG format

1. Click the **Waveform** icon.
2. Select which lead configuration you want to display from the drop-down menu:
   - 12 Leads
   - 6 x 2 Leads
   - 6 Leads
   - 3 Leads

The Waveform screen display changes to the new setting.

Hide/Show View

To allow maximum viewing of the waveforms, some views are hidden. Use the **Hide/Show View** icon to display the following:

- Show Lead Map
- Show Zoom ST
- Show ST Map
- Show Trend View (HR/METS; BP; ST Level)
- Show Average

About the Lead Map

The Lead Map diagram shows the status of each lead. Yellow indicates lead-off, and green indicates good contact.

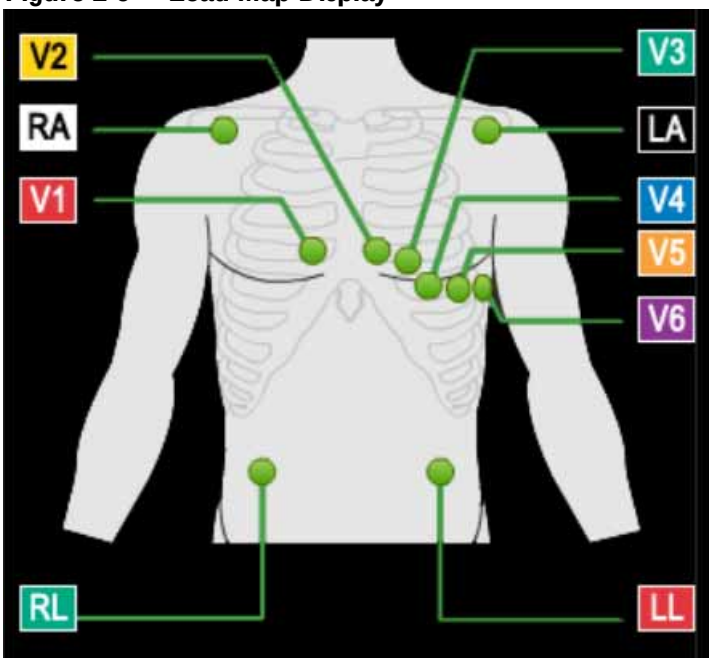
To view the Lead Map

1 Click the **Hide/Show View** icon.

2 Select Show Lead Map.

The Lead Map appears in the top-right corner of the waveform. All connections need to be green.

Figure 2-9 Lead Map Display



If a lead is off, a red “X” is displayed on the lead map and red, dashed flat line is displayed in the real-time ECG view. On the PIM, this condition is verified by a yellow LED light.

3 To close the Lead Map, click the **X** in the upper-right corner.

NOTE When a leads-off condition is detected, the leads-off indicator string will be printed as a dashed line on the report and the indicator will be saved when saving the report.

About the Zoom ST

The Zoom ST lead display shows one expanded average ECG complex, which is an averaged ECG enlarged to four times the normal size.

The absolute ST segment values and slope values are displayed for the expanded lead. This function allows you to better visualize the ST segment changes during the test.

The default ST lead is shown in the zoomed QRS window during the exercise stress test. When you begin a test, the default ST lead that is shown in the zoomed display is preconfigured in the user profile. You can select any lead as the zoomed lead from the Lead drop-down arrow.

You can also select a lead for the default setting. For default settings, see the *ST80i Installation and Configuration Guide*.

NOTE Whichever lead is selected as the Zoom ST lead, the ST change trend for this lead is also displayed in the Trend display. See "About Trend View" on page 2-22.

On the Zoom ST display, the following are displayed:

- ST Level (mm or mV)
- ST Slope (mV/s or mm/s)
- J-Point – default is 60 mm
- Default Lead – drop-down
- Reference – drop-down

NOTES ST80i can display the lead with the maximum absolute value of the ST level if you select "Max ST Level" using the drop-down arrow by the default lead.

When using the Compare icon, the averaged ECG is superimposed on the blue reference ECG so that you can compare current and reference data.

The viewing options for zoomed lead are:

Table 2-6 Zoom Lead Options

Zoom Lead Option	Description
Any individual lead - Any of the twelve leads.	This selection remains in force until you change it.
Dynamic	The system monitors all twelve leads and displays the one with the most significant ST change. The lead that appears will change automatically during the stress test; the changes are reflected on printed reports, as well.

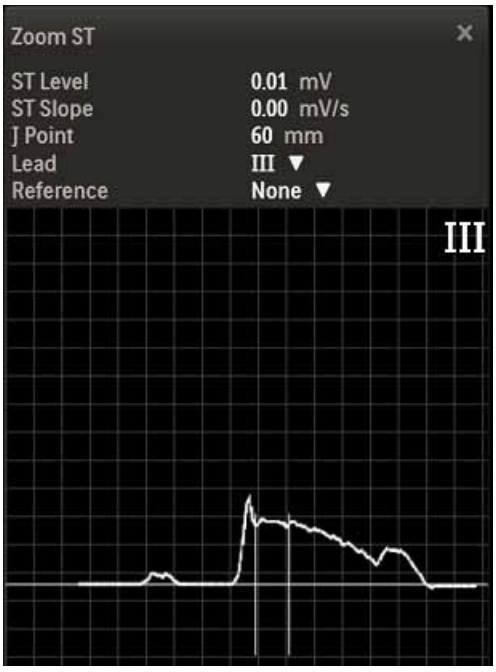
To view the Zoomed ST Lead

1 Click the **Hide/Show View** icon.

2 Select Show Zoom ST.

The default Zoom lead appears as one expanded average ECG complex on the waveform.

Figure 2-10 Zoom ST Display



3 To close, click the **X** in the upper-right corner.

To change the Zoomed ST Lead

1 Click the **Hide/Show View** icon.

2 Select Show Zoom ST

The default Zoom Lead name appears on the waveform.

3 Use the Lead drop-down menu to change to another Zoom Lead.

4 To close, click the **X** in the upper-right corner.

About the ST Map

The two-dimensional, color-coded ST map, which can help to identify ischemic areas in the myocardium, is based on both the ST deviation and ST slope. It updates every 10 seconds and can be displayed on the waveform screen.

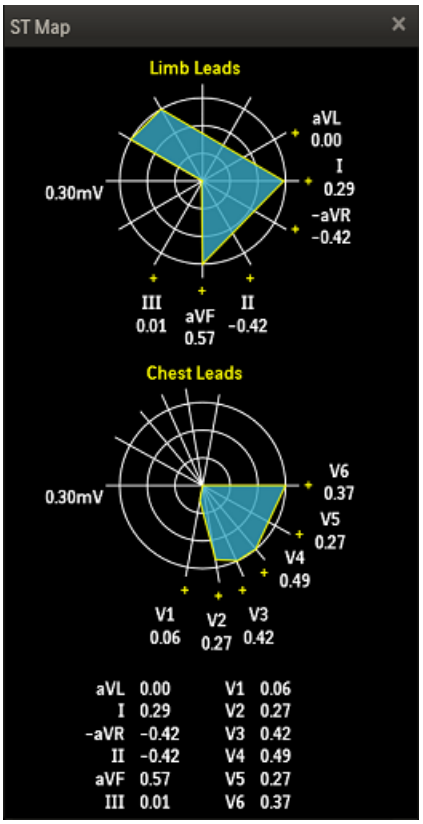
To view the ST Map

1 Click the **Hide/Show View** icon.

2 Select Show ST Map.

The ST Map displays on the waveform.

Figure 2-11 ST Map



3 Click the **X** in the upper-right corner to close the ST Map.

About Trend View

The Trends graphs show a visual indicator for the current heart rate as well as the dynamic change in heart rate. The Trends data appears in 3 charts that can be viewed at any time.

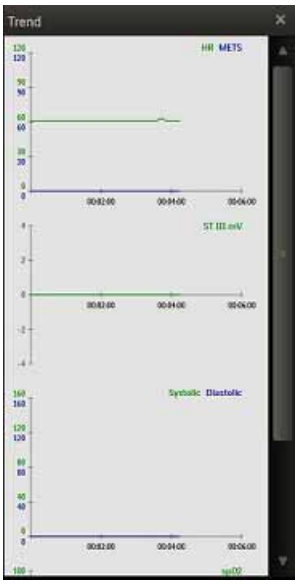
NOTE Whichever lead is selected as the Zoom ST lead, the ST change trend for this lead is also displayed in the Trend display.

To view Trends

1 Click the **Hide/Show View** icon.

2 Select Show Trend View from the drop-down menu.

Figure 2-1 Show Trend View



The Trends View has three charts:

– HR/METS

– ST J + mV

– BP (Systolic, Diastolic)

3 Click the **X** to close the Show Trends view.

About HR/METS

This two-dimensional, color-coded chart is a visual indicator for both the current heart rate and a dynamic change in heart rate. The chart's X-axis represents time, and the HR value is shown as a curve, representing the dynamic change over time. The Trend graphs of heart rate can be viewed at any time.

METS refers to the estimated metabolic equivalents.

About ST J+ mV

The J-ST time interval is preconfigured in the user profile. This setting specifies the number of milliseconds after the J-point that the ST value is measured. You cannot modify the J-ST time interval during a patient session; it must be done in advance. To modify the J-ST time interval in advance, see the *ST80i Installation and Configuration Guide*. You can, however, change the J-point on the Report screen. See "Change (J+) Point" on page 4-7 for more information.

The ST-Amplitude calculation is absolute and is shown in mm.

About BP

About the Average Complex Display

The Average Complex display shows one average complex for each of the 12 leads regardless of what lead format is being displayed.

The system displays the ST value in microvolts (or mm) for the on-screen average complexes. To change the ST value from mV to mm, see the *ST80i Installation and Configuration Guide*.

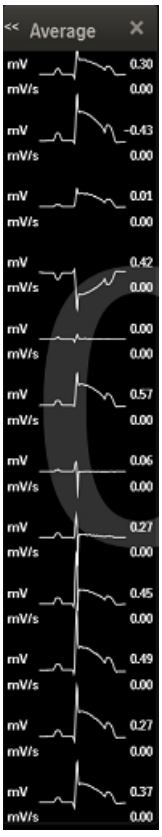
To view the Average Complex Display

1 Click the **Hide/Show View** icon.

2 Put a checkmark in the Show Average box.

The Average displays along the right-hand side of the waveform screen.

Figure 2-2 Average mV and mV/s for each Lead



3 Click **X** to close the display.

Freeze

You can print a 12-Lead ECG at any time by clicking the **Print** button. During the Exercise phase, when you select the **Freeze** icon, it freezes the most recent 10 seconds of ECG data so that you can view a specific event. A dialog box displays a Freeze image of all leads captured at the moment you clicked the **Freeze** icon.

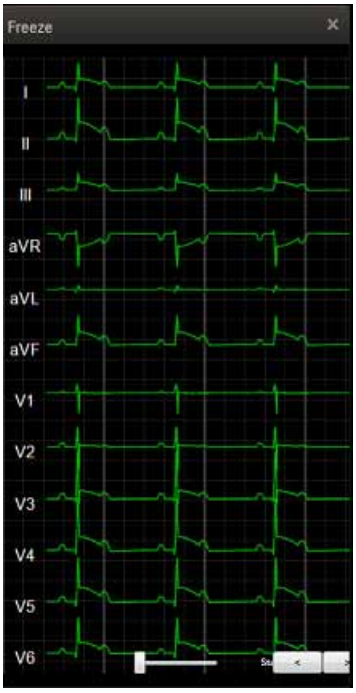
A scroll bar at the base of the Freeze image allows you to scroll to view any part of the frozen ECG.

To freeze the ECG

1 Select the **Freeze** icon.

The Freeze display appears on the right-hand side of the waveform screen.

Figure 2-3 Freeze Display



2 Use the slide bar or right/left arrows to scroll through the ECG.

3 Click **X** to close the display.

Recording an Event

Events are associated with the user profile. You can add and delete events when you create a user profile. As the test progresses, you can record events, if and when they occur. You can also add events to the drop-down list that appears by clicking the down arrow by the icon in the Toolbar.

When you record an event, ST80i generates a 12-lead ECG and documents the event name on the ECG. The system also stores the event in memory and will print it in the Rhythm Events portion of the final report. User Notes are also associated with the Event, if created. See “Note” on page 2-28 regarding the Note icon.

In addition, ST80i automatically detects an arrhythmia event–if this is enabled. To enable Arrhythmias, see the *ST80i Installation and Configuration Guide*. See also “Notifications and Alerts” on page 3-36.

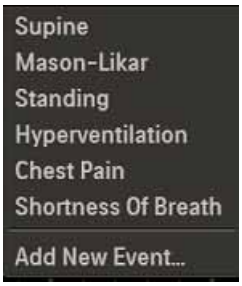
The default events include:

- Supine
- Mason-Likar
- Standing
- Hyperventilation
- Chest Pain
- Short of breath

To record an event

1 Click the **Event** button to display the Event drop-down list’

Figure 2-4 Event Drop-Down List



2 Select the event to record from the drop-down list.

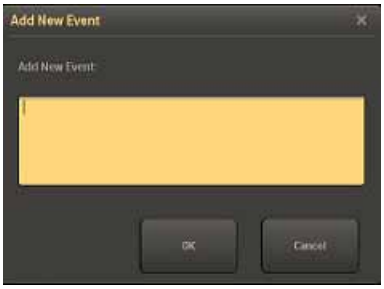
The system prints an ECG and records the event for the final report.

To add an event

1 Click the **Event** button

2 Click Add New Event from the drop-down list to display the Add New Event pop-up box.

Figure 2-5 Add New Event Window



3 Type in a name for the new event.

4 Click **OK.**

The system prints an ECG with the new event label and records the new event for the final report.

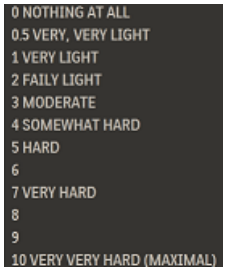
Recording RPE

The Rate of Perceived Exertion (RPE) scale provides an indication of the percentage of maximum work being done by a patient. The RPE scale subjectively rates work (physical exertion) as stated by the exercising patient. It provides a means to quantify a patient's level of exertion.

RPE scales can be expressed in two ways, 1 to 10 or 6 to 20. The scale used is associated with the selected user profile. To set the RPE scale, see the *ST80i Installation and Configuration Guide*.

When you want to record an RPE score, ask the patient to state which number or statement represents their perceived level of work. Then select the corresponding number from the drop-down list. Once the number is selected, the system prints an ECG report, noting the RPE.

Figure 2-6 RPE Drop-down List



To record the patient's RPE

1 Display the RPE drop-down list by clicking the RPE down arrow.

2 Select the RPE statement that matches what the patient reports, and click **OK**.

The system prints an ECG with the RPE statement.

3 Continue this process throughout the Exercise phase.

The RPE ECG is also held in memory, and is printed in the Rhythm Events section of the final report.

For an explanation of how this appears in the final report, see “Working with Reports” on page 4-1.

Note

During the patient session, you can add notes about the patient's progress as well as important information regarding the exercise stress test. These comments will be stored in the Notes section of Patient Demographics database and they will also appear as part of the Final Stress Report.

For an explanation of how the notes appear in the final report, see “Working with Reports” on page 4-1.

To add a Note

1 Select the **Note** icon to display a pop-up box in which you can add notes.

Figure 2-7 Note Window

2 Click **OK** to save the note.

Compare

ST80i is able to compare the current averages with reference ECG (resting, supine, hyperventilation averages) and worst case for all 12 leads.

As the heart rate increases and/or morphological changes occur, the Compare function is used to view the QRS morphology between a reference zoomed lead and a current event such as Chest Pain or Hyperventilation to compare the delta between the two.

When the zoomed lead is displayed, the averaged ECG is superimposed on the reference ECG. The white line represents current data; the reference data is blue.

To use the Compare icon

1 Select the **Hide/Show View** icon.

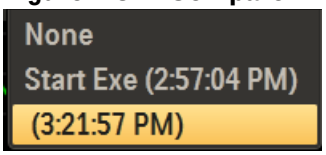
2 Select Show Zoom ST to display the zoomed QRS window. Change the default Zoomed lead, if applicable.

3 If you do not currently have a particular compare point, click the **Event** icon to select an event or create a new event. An ECG will print.

4 Select the **Compare** icon to compare the current state to when the event occurred or to an earlier point in time.

A drop-down list of current events/compare points allows you to compare the current state to when the event occurred or to an earlier point in time.

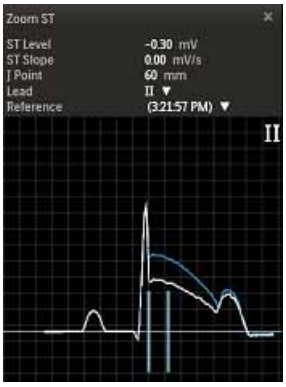
Figure 2-8 Compare Drop-Down List



5 Select an item from the list.

The current zoomed ECG appears in white; the earlier or baseline zoomed ECG appears in blue so that you can compare the ST elevation/depression of the two images.

Figure 2-9 Compared ECGs



6 Click the **X** to close the image.

Page

Use the **Page** icon to advance the thermal paper, so that the printing starts at the top of the page (at the perforation). This form-feed function for the thermal printer returns the paper to "top of form." You can also use the **Page** icon to advance the paper if there is a paper jam or after installing a new package of paper.

Relearn

--add information about this button here--

Gear (Quick Settings)

Click the **Gear/Quick Settings** icon to display the four-tabbed Quick Settings window from which you can change specific default settings that relate to the following:

- Filter
- Display
- Rhythm Print
- Sync Out

Figure 2-10 Quick Settings Window

Filter

The Filters are pre-configured in the Settings section of the application. When you log into ST80i, the active settings of the filters are set to a stored default set that are associated with your user profile.

The ECG data is stored in its unfiltered state (0.02 - 300Hz, all filters off) and user-selected settings are stored with the ECG."

NOTES The ECG data is filtered at 0.05-150Hz before being analyzed by the algorithm. This filter is called the algorithm filter and cannot be turned off by user. The algorithm filter is independent from other filters and is neither controlled by the user nor affects the saved ECG data.

All filters can be turned on or off as needed to improve signal quality except for the algorithm filter (as described above) and minimum filters (0.02Hz high pass filter and 300Hz low pass filter).

Using the Filter tab in Quick Settings, you can change the default settings.

The options include:

- Low Pass (LP) Filter: 40Hz, 100Hz, 150Hz, 300Hz
- High Pass (HP) Filter: 0.02Hz, 0.05Hz, 0.15Hz

- AC Filter: 50Hz, 60Hz, None
- Artifact Filter: On, Off
- Smart Filter: On, Off

The same filter settings apply to both displayed and printed waveforms. The filter settings are printed with the report.

To change the Filter settings

1. Select the **Gear (Quick Settings) i**con.
2. Select the Filter tab.
3. Change or modify each filter, as required.
4. Click **OK** to save changes.

For more information, see “Filtering” on page 3-25.

Display

On the Display tab, you can change the Limb Gain, Chest Gain, and Speed.

To change the Display settings

1. Click the **Gear (Quick Settings)** icon.
2. Select the Display tab.
3. Use the drop-down arrow to adjust the Limb Gain setting.
4. Change the Chest Gain setting:
   - Full
   - Half
5. Change the speed:
   - 25 mm/s
   - 50 mm/s
6. Click **OK** to save your settings.

Rhythm Print

Before you select the **Rhythm Print** icon from the Procedure bar to print a continuous strip, you can modify your settings based on the following:

- Leads
- Limb Gain
- Chest Gain
- Speed

To change the Rhythm Print settings

1. Click the **Gear (Quick Settings)** icon.
2. Select the Rhythm Print tab.
3. Place a checkmark for each lead you want to print. (1 - 13 leads are available.)
4. Use the drop-down arrow to adjust the Limb Gain setting. (2.5, 5, 10, 20 mm/mv)
5. Change the Chest Gain setting:
   - Full
   - Half
6. Use the drop-down arrow to adjust the Speed. (5, 10, 25, 50 mm/sec)
7. Click **OK** to save your settings.

Sync Out

ST80i supports two analog ECG output signals and one TTL ECG Sync Output on the Advanced Interface Module (AIM).

- Analog ECG Output - for synchronization with ECHO device for Stress-Echo procedures. This signal is not to be considered as diagnostic quality.
- TTL Sync Output - for QRS gating required by the Tango SunTech implementation of NIBP measurement

CAUTION Sync ECG output signals are not real-time; therefore, they are not diagnostic quality and should not be used for analysis.

They are pre-configured as part of the user profile. However, they can be changed during the patient session.

See the *ST80i Installation and Configuration Guide* for how to configure Sync Out settings in the user profile.

To change Sync Out settings

1. Select the **Gear (Quick Settings)** icon.
2. Select the Sync Out tab.
3. Use the drop-down menu to modify the following:
   - Analog Out 1 → Amplify Ratio [drop-down]
     - [Example: Analog Out: I; Amplify Ratio: 3 mV/V]
     - Options: None; Leads I - V6
   - Analog Out 2 → Amplify Ratio [drop-down]
     - [Example: Analog Out 2: None; Amplify Ratio: 1 mV/V
     - Options: None; Leads I - V6
   - TTL Out → Polarity/Duration (ms) [drop-down]
     - [Example: TTL Out: None; Polarity: Positive; Duration: 50 ms]
     - Options: None; Leads I - V6
   - Polarity (Positive/Negative)
   - Duration: default is 100 ms.
4. Click **OK**.

3

The Patient Session

Overview

A patient session is the period of time when the exercise stress test is performed, and waveforms are acquired and processed for a single patient. Patient information is linked with all waveform data acquired during the patient session. The session starts when you begin a new exam and gather pre-exercise data, and lasts through generation of the final report.

In ST80i, the exercise stress test begins with the Pre Exercise phase and ends with the Report phase.

- Pre Exercise
- Exercise
- Recovery (and Post-Recovery)
- Report

CAUTION Do not run any other applications, including screen savers, when performing an exercise stress test. Once the test has begun, the ST80i application does not allow you to access other system functions.

This chapter provides the following information:

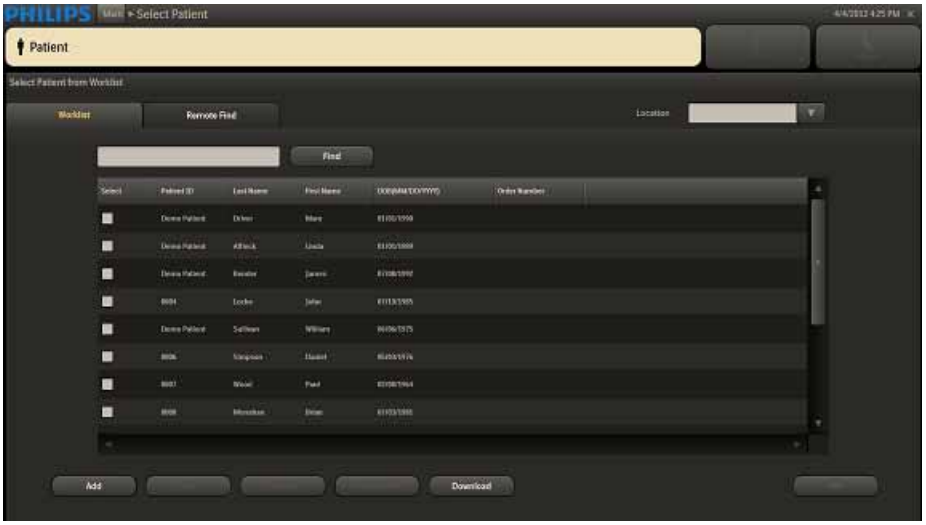
Using the Patient Worklist

When you click **Patient** on the Main screen, you are taken to the Select Patient screen, where you begin a patient session by selecting the patient for the exam.

The Select Patient screen includes two tabs:

- Worklist
- Remote Find

Figure 3-1 Select Patient Screen



Use the Worklist tab to manage patient information. The Worklist enables you to pre-register up to 200 patients. The Worklist database is populated by downloading patient orders or ADT data from a Hospital Information System (HIS), by manually entering information into the Worklist window, or by remote retrieval of information.

Use the Remote Find tab to do a remote search for a patient using several data points. ST80i provides an interface with the Philips ECG Gateway or a DICOM server so that you can do the following before conducting an exercise stress test:

- Download a patient's data from DICOM server via ECG Gateway
- Download a patient's orders or ADT data from the hospital HIS system (via ECG Gateway)

Worklist Tab

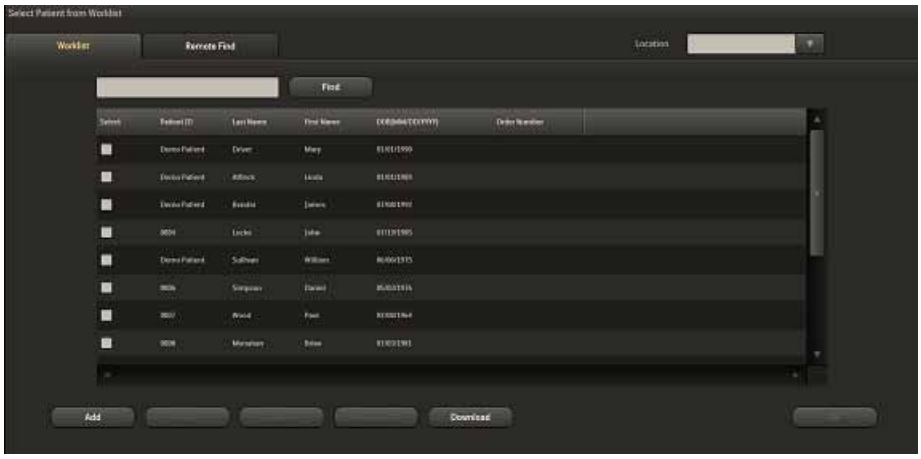
The Worklist tab of the Select Patient from Worklist screen is used to manage the patient information list, including:

- Adding a new patient
- Finding a patient

- Editing a patient profile
- Deleting one or more patient information records
- Downloading orders or pre-registered patient information
- Selecting a patient to begin the exercise stress test

On the Worklist tab, you can also use the column headings to sort each list.

Figure 3-2 Worklist Tab



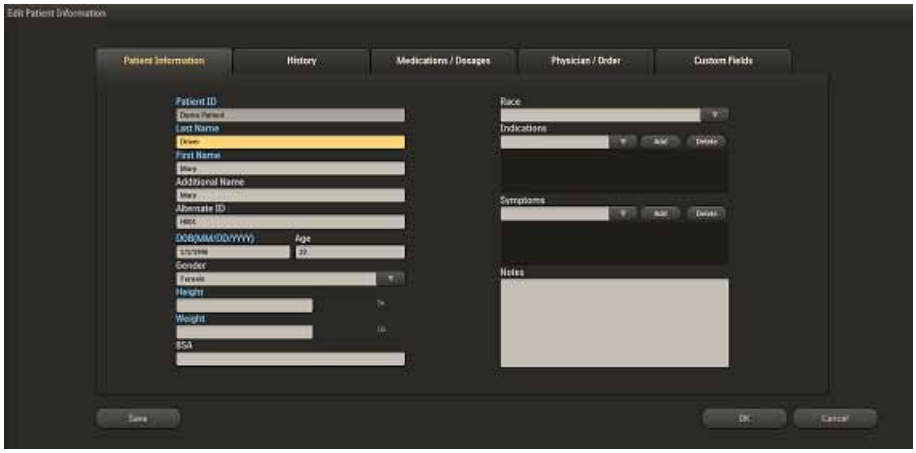
Patient Information Management

ST80i displays and reports key patient demographic information such as the patient name, hospital ID number, etc. Some settings are mandatory and configurable. Some settings are set to ON or OFF.

There are two ways to access Patient Demographic information:

- From the Worklist tab before the test:
  1. Place a checkmark by the patient's name.
  2. Select the **Edit** button.
     The Edit Patient Information screen is displayed.
- From the Test screen during a patient session:
  1. Click on the patient's name from the top bar.
     The Edit Patient Information screen is displayed.

Figure 3-3 Edit Patient Information Screen



You can also access this information from the Report screen. See “Working with Reports” on page 4-1.

Patient Information Fields

ST80i supports predefined and user-defined patient information fields. The predefined patient information fields are shown in the Patient Information tab of the Edit Patient Information screen. The patient information fields are configured as mandatory or not. Mandatory fields are displayed in blue text.

CAUTION For better algorithm output, the Patient Information Fields that may affect algorithm output need to be enabled and complete. At a minimum, the Patient ID, Last Name, First Name, DOB, and Gender must be configured as mandatory fields that will be identified on the Test screen.

To configure or change mandatory patient information fields, see the *ST80i Installation and Configuration Guide*.

CAUTION Specific patient data is required for each interpretation. If entered patient data are found to be incorrect, the ECG file may be edited and a new display and/or report can be printed.

Add a New Patient to the Worklist

To manually add a new patient name to the Worklist

1. Click the **Add** button.
2. In the Add New Patient screen, fill in the patient name and patient information in the required fields for each of the following tabs:

- Patient Information
- History
- Medications/Dosage
- Physician/Order
- Custom Fields

3 If you want to:

- Save the information and return to the Worklist, click **Save**.
- Save the information and begin the stress test, click **OK**.

NOTE When mandatory fields are missing, you will be warned with a pop-up message box. If these fields are changed, a warning message pops up and the resting ECG will be re-interpreted.

Find a Patient

You can find a patient already listed in the Worklist by using specific demographic information as search criteria.

To find a patient in the Worklist

1 Type one of the following into the search field: Patient ID, last name, first name, or order number.

2 Click **Find**.

The Worklist displays only the patient(s) matching the search criteria.

3 Click the **Back** button to restore the full list of names.

Edit Patient Information

In Worklist, you can edit or review patient information by using the **Edit** button.

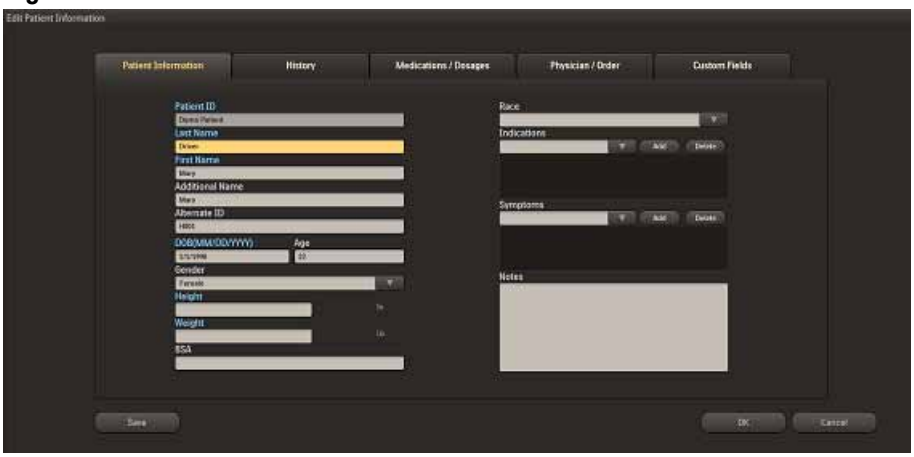
When you select a patient name, the **Edit** button becomes active.

To edit patient information in the Worklist

1 Place a checkmark by the patient's name.

2 Click the **Edit** button to open the Edit Patient Information screen.

Figure 3-4 Edit Patient Information Screen



3 Update or edit the patient information in each of the following tabs, as required:

- Patient Information
- History
- Medications/Dosage
- Physician/Order
- Custom Fields

4 If you want to:

- Save the information and return to the Worklist, click **Save**.
- Save the information and begin the stress test, click **OK**.

NOTE When mandatory fields are missing, you will be warned.

Delete a Patient Name

You can delete one or many patients from the Worklist.

To delete a patient name from the Worklist

1 Place a checkmark by the patient's name. You can check more than one patient name to delete.

2 Click the **Delete** button.

3 Select **Yes** from the pop-up box: “Delete record(s) from Worklist.”

Figure 3-5 Delete Record(s) from Worklist Window

Download Preregistered Patient Information

With ST80i, you are able to download preregistered patient information by accessing the order or ADT server via the network. The local patient information that you download from remote server or manually add will be stored in a local database. This optional feature permits the creation of a preregistered patient list.

To download orders -- *procedure in development...*

1 Click **Location**

2

3

Review a Previous ECG

To review a patient's previous ECG Report

1 Place a checkmark by the patient's name.

2 Click the **Previous ECG** button.

The Previous ECG Report List is displayed.

Figure 3-6 Previous ECG Report List Screen

3 Place a checkmark by the patient's name.

4 Click the **View Report** button.

The report opens in pdf format.

Figure 3-1 Report Screen

5 Click the **Back** button to return to the Select Patient from Worklist screen.

Select a Patient

When you are ready begin the patient session for a patient, select his or her name from the Worklist.

To select a patient to begin the patient session

1 Place a checkmark by the patient's name.

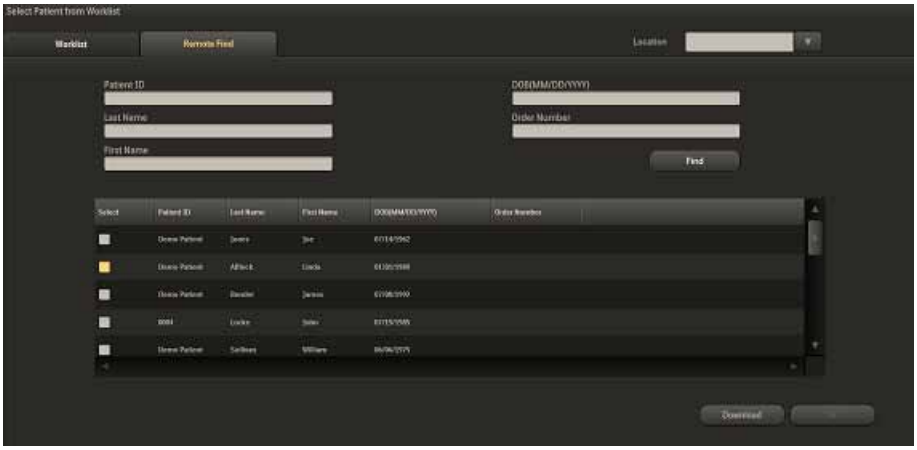
2 Click **OK** or press Enter.

This brings you to the first screen of the test: Pre Exercise

Remote Find Tab

The Remote Find tab of the Select Patient from Worklist screen allows you to do a remote search for a patient using several data points. With this feature, you are able to select one or more entries from the search results list and save them to the Worklist.

Figure 3-2 Remote Find Tab



To do a Remote Find

1. Select the location from the Location drop-down list.
2. Fill in one or all of the following fields:
   - Patient ID
   - Last Name
   - First Name
   - DOB (MM/DD/YYYY)
   - Order Number
3. Click the **Find** button.

   Patient's name appears in the Remote Find list.
4. Place a checkmark by the patient's name.
5. Click the **OK** button to start a patient session.

Before the Patient Session

The exercise stress test process requires some advance preparation before running the patient session. Advance preparation includes the following:

- Checking the Wireless Patient Interface Module (PIM)
- Checking the equipment connection (treadmill/ergometer), if used
- Setting up the Pharma test

Once advance preparation is complete, the patient session follows a series of typical steps - from preparing the patient to the final review of the exam.

Wireless Patient Interface Module (PIM)

The wireless PIM is a small data acquisition device that samples patient ECG signals and sends the processed signals to ST80i. The wireless PIM assembly contains the signal acquisition electronics, patient isolation circuits, and system interface circuits. The patient lead set connects to the patient electrodes on one end and plugs into the wireless PIM on the other.

Figure 3-3 Wireless PIM

The wireless PIM digitizes the ECG signal and down-samples the ECG data before transmitting ECG data to ST80i. The wireless PIM uses high and low pass filters to produce filtered ECG data within certain band.

The wireless PIM performs lead signal quality detection to determine if a lead is not connected to patient or electrode/patient contact impedance is excessively high.

The wireless PIM can also be commanded by the host application to transmit on a user-selected channel to manually override the automatic system driven settings to avoid wireless interference. See the *ST80i Installation and Configuration Guide* for information on configuring a wireless channel for communication.

The wireless PIM shows the following information:

- Wireless signal quality indicator:

  Wireless performance and signal strength are monitored on the currently used RF channel. The wireless PIM's signal quality icon indicates the connection status. If a channel has excessive interference, the wireless PIM will automatically determine a clearer channel with higher signal strength and coordinate with the Advanced Interface Module (AIM) to switch to the new channel.

- Lead-off indication for every lead:

  ST80i recognizes when an electrode is not connected and displays that information on the graphic of a human torso on both the wireless PIM and ST80i interface.

- Power indication for battery:

  The wireless PIM is battery-powered and the battery voltage is monitored to ensure that the battery is not overly discharged. The remaining battery capacity is displayed in the wireless PIM's power indicator lights within the battery icon. These lights blink every 5 seconds when the PIM is in use.

  In addition, when all patient leads are being connected prior to a test, a low-battery alert warns if there is not enough capacity in the battery to complete test.

  ST80i also provides an audible and visual alert on the application screen as a warning that the battery is discharged to the point where PIM is expected to shut down shortly.

The wireless PIM uses off-the-shelf (OTS) disposable AA alkaline batteries for its power source. For the disposable AA battery, the system has been designed to provide approximately one week of battery service life for a "typical" user environment. .

CAUTION ST80i only supports 1.5V AA alkaline batteries for the PIM. Replace the battery if a low-battery alert appears before the stress test starts.

CAUTION If you use off-the-shelf rechargeable AA-size batteries, the remaining capacity indication may be inaccurate.

CAUTION If you use OTS rechargeable batteries, you will need to provide a compatible recharger unit for their batteries that is independent of the ST80i. To ensure safe use and adequate maintenance of rechargeable batteries, follow the battery manufacturer's instructions for use.

When using the wireless PIM, refer to the *ST80i Wireless Patient Interface Module Instructions for Use* for details on its preparation, configuration, and use.

If your facility is using more than one PIM, each one must be added to the ST80i application under Settings (System Settings; I/O Devices). When you connect the patient to one of the PIM devices, you also need to verify the address on the device with the address that shows up on the Pre Exercise screen.

To preconfigure multiple PIM addresses, see the *ST80i Installation and Configuration Guide*.

Checking the Treadmill/Ergometer Connection

During the entire stress test, the host-side application validates the response from treadmill/ergometer to ensure the communication between PC and treadmill/ergometer is successful.

Starting a Patient Session

When you select a patient from the Worklist for the stress test, you are immediately brought to the Pre Exercise screen. Based on your user account settings at log-in, a preconfigured profile is loaded for the stress test protocol.

Select the Patient

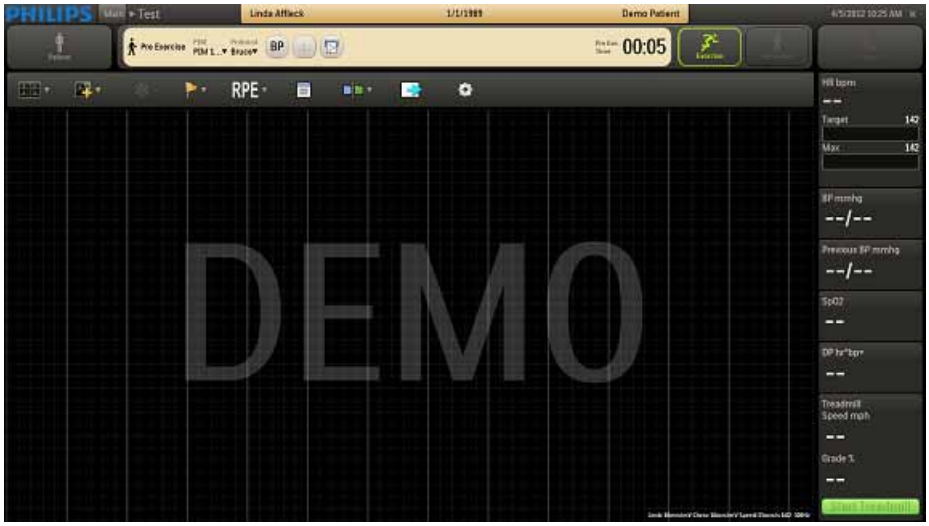
To select a patient from the Worklist

1 Click **Patient** on the Main screen.

2 Place a checkmark in the patient name line and click **OK,** or double-click the patient's name.

The Pre Exercise screen is displayed. The patient's name and date of birth appear on the Title Bar along with the patient ID. The selected protocol is shown on the Procedure Bar.

Figure 3-4 Pre Exercise Screen



By default, the application displays the real-time ECG waveforms in the format specified in the selected user profile.

To change the real-time ECG display, see "Using the Toolbar Icons" on page 2-15.

When Bruce is selected as the protocol, the **Start Treadmill** button appears in the Side Panel.

If you select Cycle as the protocol for the patient, the **Load Ergometer** button appears instead.

Select the Wireless PIM

The wireless PIM contains a power on/power off button. Before connecting a patient to the PIM, check the battery status and the wireless signal quality. You will also need to confirm that you are using the right PIM by checking the PIM address.

By default, you will see PIM1 as the first device on the Pre Exercise screen. When you click on the device name, a unique address appears which is used to identify that specific PIM. If there are multiple PIMs registered, they will appear as named during preconfiguration.

To select the wireless PIM

1. Click the PIM drop-down menu.
2. Click the PIM device to be used (by name).
3. To ensure a correct match, confirm the unique address on the wireless device with the one you have selected on the Pre Exercise screen.
4. Press the PIM button on the device to power it on (if it is powered off).

   The PIM wireless status gives feedback that the PIM is selected to communicate with the application.

CAUTION The user should follow the correct procedure to select the PIM when multiple PIMs are detected.

To ensure proper wireless function of the PIM

- Press the PIM's "light" button to display battery strength.

  A battery icon on the ST80i exercise screen also shows the remaining capacity of the wireless PIM battery.

ST80i also provides an audible and visual alert on the application screen as a warning that battery is discharged to the point where PIM is expected to shut down shortly.

NOTE To save the battery power, the PIM can be preconfigured to power off automatically when there is no action on the PIM for a predefined period.

To preconfigure PIM Power Saving, see the *ST80i Installation and Configuration Guide*.

Preparing the Patient

Good ECG technique is very important to achieve the best quality results.

Instructing the Patient about the Test

Before attaching the electrodes, greet the patient and explain the procedure. Explaining the procedure decreases anxiety and informs the patient about what to expect. You may also click the **Explain Test** button on the Main screen to play an audio file that explains the test to the patient.

NOTE ST80i ships with a default audio file that explains the exercise stress test; however, you may record your own audio file and configure ST80i to play this file when the user clicks the **Explain Test** button. For more information, see the *ST80i Installation and Configuration Guide*.

- Privacy is important to relaxation. When possible, prepare the patient in a quiet room or area where others cannot see the patient.
- Reassure the patient that the procedure is painless.
- Make sure the patient is comfortable. The patient's arms and hands must be relaxed.
- Instruct the patient to rest their hands on the handrails and not grasp the handrails tightly.

The more relaxed the patient is, the less the ECG will be affected by noise.

Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifact that distorts the ECG signal. By performing methodical skin preparation, you greatly reduce the potential for myographic noise and baseline wander, ensuring high-quality printouts and displayed data. There is a natural resistance on the skin surface due to dry, dead epidermal cells, oils, and dirt.

To prepare the skin

1. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.
2. Wash the area thoroughly with soap and water.

NOTE Do not use alcohol to clean the skin.

3. Dry the skin vigorously with a gauze pad to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oil.
4. Use an abrading pad to lightly scratch an “X” pattern into the skin, taking care to avoid excessive abrading.

Attaching the Electrodes/Lead Wires

Placement of the electrodes changes depending on the stage:

- Supine for a resting or baseline ECG
- Standing for Exercise Phase

ST80i supports the use of 12-lead wireless PIMs. The 12-lead wireless PIMs connect to the AIM and support 10 electrodes. Using AAMI/IEC labeling, these electrodes are:

- Right Leg [RL/N]
- Left Leg [LL/F]
- Right Arm [RA/R]
- Left Arm [LA/L]
- Chest leads [V1/C1, V2/C2, V3/C3, V4/C4, V5/C5, and V6/C6]

All leads are acquired simultaneously. Review the following lead wire labeling and electrode placement information in Figure 3-5 and Table 3-1 to ensure a quality ECG.

Figure 3-5 12-Lead Electrode Placement (AAMI/IEC)

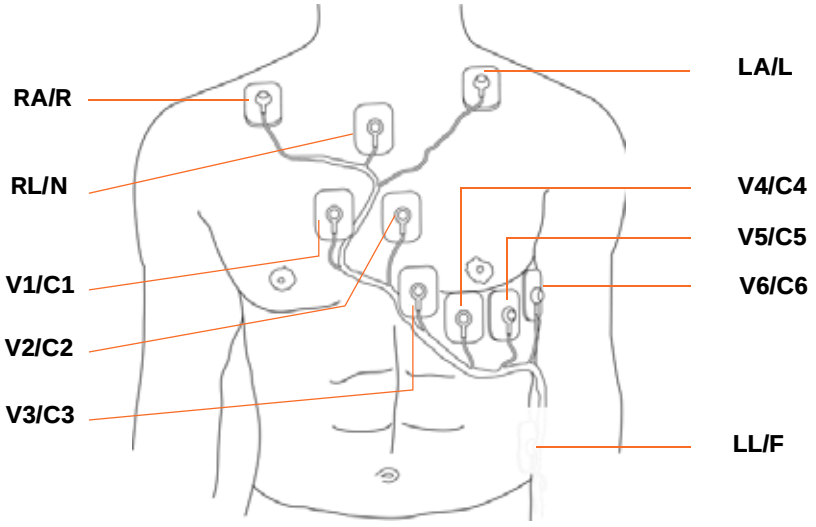


Table 3-1 Leads and positioning

AAMI Lead	IEC Lead	Electrode Position
V1	C1	Right side of the sternum in the 4th intercostal space
V2	C2	Left side of the sternum in the 4th intercostal space
V3	C3	Midway between V2 and V4
V4	C4	Left midclavicular line in the 5th intercostal space
V5	C5	Between V4 and V6
V6	C6	5th intercostal space, left midaxillary

Table 3-1 Leads and positioning

AAMI Lead	IEC Lead	Electrode Position
		Place the limb electrodes for the arm directly on the clavicle bones (away from major muscles)
		
		Below V6 on the ribcage
		On the sternum, midway between the clavicle and the 4th intercostal space

To attach the electrodes to the patient

1 Place the gel area of the electrode over the center of the prepared area, using the positioning described in Table 3-1 and illustrated in Figure 3-5; then press the adhesive ring into place.

- Avoid pressing the center of the gel area; this might hinder conduction.
- Place the electrodes on the soft tissue of the arms, avoiding muscle. See limb lead placements notes next.

Lead placement is similar to standard 12-Lead ECG placement; however, limb leads are modified, as follows:

- Right Arm and Left Arm leads should be placed close to the shoulders on the clavicle bone, away from the muscular areas to avoid muscle interference.
- The Right Leg lead is typically placed on the sternum midway between the arm leads and V1 and V2 leads.
- The Left Leg lead should be placed on a rib, below V6 by about 2 fingers, in the lower left area of the patient's chest (avoiding flabby areas and the belt). This may need adjustment depending on body habits.

2 Ensure the electrodes are firmly attached.

A good test for firm electrode contact is to try to move it. If it moves easily, the electrode connection is too loose. Do not allow electrodes to move in any way.

3 Have the patient raise their arms over their head. This will help verify good lead placement and no strain on the electrodes.

Change from Limb Lead to Mason-Likar

To attach the electrodes for the Supine (Resting) phase

1. Place the upper body electrodes on the patient.
2. Have the patient lie down.
3. Attach the leg electrodes.
4. Take the BP measurement.
5. Record the ECG.
6. Label the ECG “Supine.”

To attach the electrodes for the *Exercise Phase* (Standing)

1. Disconnect the limb leads from the patient.
2. Remove the leg electrodes.
3. Hold the PIM as the patient stands.
4. Place the limb electrodes on the torso.
5. Attach the limb leads.
6. Put on the belt and PIM.
7. With the patient standing, record the ECG and label “Standing.”
8. The patient is now ready to move to the exercise device.
9. Explain the test.

Connecting the Patient to the Wireless PIM

All of the ST80i lead sets are designed to share the same connector that will plug into the mating connector on the wireless PIM. Refer to the *ST80i Wireless Patient Module Instructions for Use* for details on its preparation, configuration, and use.

To connect the patient to the wireless PIM

1. Plug the lead set connector into the mating connector on the wireless PIM.

   Ensure that lead wires do not bump or rub against anything.
2. Place the wireless PIM into the PIM holder. The PIM holder is designed to keep the PIM steady, thereby minimizing movement of the lead wires and ECG signal artifacts. The PIM holder is adjustable up to a patient waist size of 57".

Wireless PIM Button Functions

The wireless PIM has one button that you can use to:

- Power on/off the PIM
- Check PIM battery status, wireless link quality, and lead contact quality

When requested to check battery status, the wireless PIM will provide indication of estimated battery power remaining.

When requested to check status of connection to the host system, the wireless PIM will indicate relative signal strength based on the measured signal quality for the link to the host receiver.

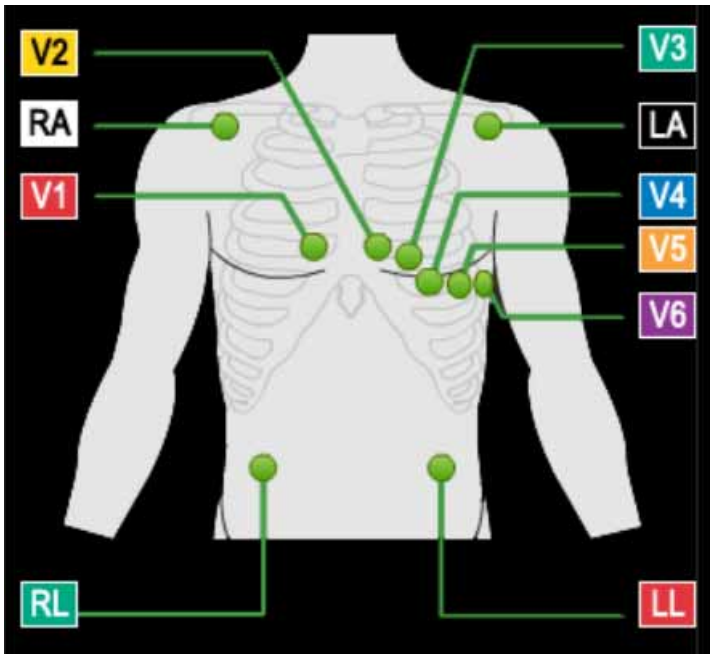
When requested to check lead/electrode connections, the wireless PIM will indicate “Poor Lead Signal Quality” condition for any patient electrode connection where the measured impedance is considered excessively high for good quality, low noise ECG measurements. You are able to check the lead signal quality of lead connections while hooking up and preparing patient in an area outside of the range of the system’s radio connection.

Checking the Lead Map

To check the Lead Map

- Select Show Lead Map from the **Hide/Show View** icon on the Pre Exercise or Exercise screen. A color-coded anatomical diagram displays the lead connections.

Figure 3-6 Lead Connections



If a lead is off, a red "X" is displayed on the lead map and red, dashed flat line is displayed in the real-time ECG view. On the PIM, this condition is verified by a yellow LED light.

For more details on checking the lead quality connection, see "About the Lead Map" on page 2-19.

For more details about adjusting the filter, see "Gear (Quick Settings)" on page 2-30.

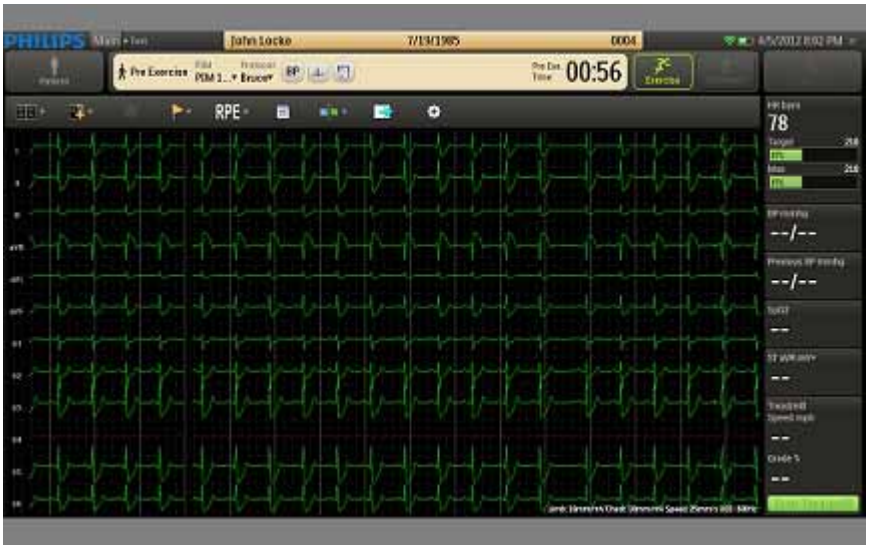
NOTE Using medical tape to fix the lead wires to the chest may help to minimize strain applied to electrode connections, thus reducing noise and possibility of leads-off condition occurring.

Checking Signal Quality

ST80i can recognize when an electrode is not connected, and display that information on both the wireless PIM and the Exercise screen. As you adjust the electrodes, the display is updated to reflect changes in the connectivity of the signal. The lead-off condition will be saved with the data and will be indicated on any printed reports which contain that data.

The waveform appears on the real-time display as green. When a lead-off condition is detected, the corresponding lead(s) will be indicated on the real-time display as a red dashed line; when printed, this will also appear as a dashed line.

Figure 3-7 Red Dashed Line Showing Leads-Off Condition for V4



ST80i will also provide an indication to the operator when the front-end is inoperative and cannot acquire signal. The indications are lead-off on all leads and the wireless signal quality indicator lights. This condition will be saved with the data and will be indicated on any printed reports which contain that data.

Figure 3-8 Faulty Lead Display Example (V1)

If the screen shows one or more faulty lead connections, re-prep the patient (page 3-17) and replace the electrodes (page 3-18), as necessary, until the display shows satisfactory tracings.

Filtering

When you open the ST80i application, the active settings of the filters are associated with your user profile. The same filter settings apply to both displayed and printed waveforms. The filter settings are printed with the report.

The smart filter can be enabled or disabled through the Config screen User Profile tab's **Filters** button. The same filter settings apply to both displayed and printed waveforms. The filter settings are printed with the report.

The filtering techniques developed for ST80i permit the user to identify any clinically significant ST deviation and will not degrade the integrity of the relevant ECG signal content, specifically the ST segment (deviation and slope). This capability is especially important during stages of exercise (stage three and later) where more motion and muscle artifact is present, which could otherwise obscure the ST deviation.

The ECG data is stored in its unfiltered state (0.02 – 300Hz, all filters off) and user-selected settings are stored with the ECG.

NOTES The ECG data is filtered at 0.05-150Hz before being analyzed by the algorithm. This filter is called the algorithm filter and cannot be turned off by user. The algorithm filter is independent from other filters and is neither controlled by the user nor affects the saved ECG data.

All filters can be turned on or off as needed to improve signal quality except for the algorithm filter (as described above) and minimum filters (0.02Hz high pass filter and 300Hz low pass filter).

If needed, you can change the default filter settings. For details on filter settings, see "Gear (Quick Settings)" on page 2-30.

Sync Output

ST80i supports two analog ECG output signals and one TTL ECG Sync output on the AIM. The AIM accepts real-time ECG data from the wireless PIM and dispatches the data to the PC and output channels. This signal serves as a synchronization signal for coordination of timing between ST80i and another device, such as imaging devices.

ST80i also supports the TTL and Analog output options, which allow selectable ECG signals to be sent to Echo system, NIBP and/or SpO_2 for further clinical analysis.

The analog-out signals are amplified.

TTL/Analog Output Option:

- Specifying the Sync Lead
  - User can select the ECG lead used for the TTL/Analog Output.

The source signal of the analog ECG and TTL Sync for each output channel can be selected by software from any of the available ECG leads separately. The amplify ratio for the Analog ECG Output can also be configured independently.

To change Analog and/or TTL Output settings during a patient session, see “Gear (Quick Settings)” on page 2-30.

To configure Analog and TTL Output, see the *ST80i Installation and Configuration Guide*.

WARNING Both analog ECG output and TTL sync output are not in real time: there is a delay between the patient’s physiological activity and the appearance of its representative signal at the external port. This signal should not be used for analysis.

NOTES ST80i monitors interference and signal strength and automatically selects a clearer frequency band when excessive interference exists.

Software design also ensures that the waveform or lead label can be correctly displayed, stored, and printed, to avoid data conversion or lead combination errors.

Pre Exercise Phase

The Pre Exercise phase is used to start the patient on the treadmill or the ergometer. The phase is preset to run for 3 minutes with the speed setting on 01:00 and the elevation is set at 0%.

Figure 3-9 Treadmill Speed and Grade

Note that the Pre Exercise time is separate from the Exercise time.

Before the Pre Exercise phase begins with the patient on the treadmill, the following steps are recommended:

- Baseline ECG (resting or standing)
- Baseline Blood Pressure - manual or NIBP
- Baseline Sp02

Static ECG Resting Interpretation

Once the waveforms are satisfactory, you are ready to acquire a baseline (resting or standing) ECG. ST80i allows you to acquire and print a 12-lead resting ECG with or without interpretation when the patient is supine or when using the Mason-Likar lead placement. This data will appear as part of the Final ECG Report.

ST80i will provide resting ECG interpretation for all available lead configurations, using the latest Philips DXL algorithm at resting ECG for traditional limb lead placement as well as Mason Likar.

WARNING To get the most accurate interpretation during resting ECG, use traditional limb lead placement.

When the algorithm finds excessive artifact or AC noise, it will give a related warning/error string. The string will be printed on the report and be saved when saving the report. The algorithm also reports wrong lead placement.

See “Filtering” on page 3-25 regarding artifact or AC noise.

To acquire a *resting* ECG without interpretation

1 Have the patient in a supine position.

2 Click **12 Leads Print** button on the Toolbar to obtain a 12-lead resting ECG without interpretation.

To obtain a 12-lead *resting* ECG without interpretation:

1 Click the **Event** button.

2 From the drop-down menu, select Supine.

To acquire a 12-lead *standing* ECG without interpretation

1 Have the patient in a standing position.

2 Change the lead position to Mason-Likar.

3 Click the **Event** button.

4 From the drop-down menu, select Standing.

5 Click the **12 Leads Print** button on the Toolbar to obtain a 12-lead resting ECG without interpretation.

After a few seconds, the ST80i system prints a full 12-lead resting ECG with measurements.

To obtain a 12-lead *resting* ECG with interpretation

▶ Select an event while in Pre Exercise.

After a few seconds, the ST80i system prints a full 12-lead resting ECG with measurements and interpretation text.

The next step is to connect the patient to the blood pressure monitor and record a baseline blood pressure.

NIBP & SpO_2

ST80i supports optional SpO_2 and motion-tolerant Non-Invasive Blood Pressure (NIBP) devices. ST80i automatically collects the NIBP through a cuff. The patient's SpO_2 is collected in real-time through a sensor.

NIBP and SpO_2 are real-time numeric displays for the NIBP and SpO2 values for an entire study or for a single instance. They can be manually measured and the values can be overridden.

During the stress test, NIBP and SpO_2 are measured according to the intervals defined in the exercise protocol and are continually displayed on the screen. This will be recorded in the BPmmhg field in the Side Panel and also on the ECG. The SpO_2 measurement will also be recorded in the Side Panel in the SpO_2 field.

If enabled, there are also audible prompts for NIBP and SpO_2. To enable audio prompts, see the *ST80i Installation and Configuration Guide*.

To connect the patient to the NIBP device

1. Place the cuff on the patient.
2. Take a pre-stress NIBP connection test to determine if the cuff is correctly placed on the patient and to ensure NIBP measurements throughout the stress test.

To connect the patient to an SpO_2 sensor

- Place the SpO_2 sensor on the patient's finger. connection test. The screen should display an SpO_2 value.

Override NIBP and SpO_2

When you enter or acquire blood pressure values according to the pre-programmed automatic prompts or at any other times during the test, for each recording, the blood pressure value, phase, and total time of the phase at the time of the acquisition are captured.

The automatic timing of blood pressure measurements is established in the exercise protocol. You can, however, take blood pressure measurements at any time during each stage by using the **BP** button. Or you can enter the measurement manually, after taking the patient's blood pressure.

When you override the values of NIBP and SpO_2, they will be displayed in the Stage Report and the Final Stress Report.

NOTE Once the NIBP or SpO_2 is manually overwritten, ST80i no longer updates the real-time NIBP or SpO_2 values from the NIBP monitor.

To take a blood pressure measurement (if the patient is connected to a blood pressure monitor) other than a timed BP

- Click the **BP** button.

  The current blood pressure measurement displays in the BP mmhg field.

  The previous blood pressure measurement displays in the Previous BP mmhg field.

To manually enter the blood pressure measurement when no NIBP device is connected

1. After you take the patient's blood pressure, click the BP mmhg field.
2. In this field, insert the latest blood pressure measurements.
3. Click **OK**.

   The display shows the manually entered measurements.

   The previous blood pressure measurement displays in the Previous BP mmhg field.

To override the SpO2 -- *procedure in developement---*

NOTE ST80i software validates the input values of NIBP and SpO_2 before they take effect to ensure that the numbers fall within an expected physiological range.

For how this information will be displayed in the Final Report, see “Working with Reports” on page 4-1.

After taking the baseline measurements, you are now ready to instruct the patient in the proper use of the equipment.

Starting the Patient on the Treadmill or Ergometer

The start and stop control for the treadmill or ergometer appears in the side panel. There is also a start and stop button on the treadmill.

You can also manually control the speed and grade of the treadmill during any stage in the Exercise test. See “Controlling the Treadmill or Ergometer” on page 3-35.

To start the patient on the treadmill

1. Show the patient the location of the emergency stop button.
2. Have the patient straddle the belt.
3. In the ST80i application, click **Start Treadmill.**

   This button changes to **Stop Treadmill.**

The treadmill starts at the preselected speed and elevation set for the protocol.

4 Allow the patient to get acclimated to the movement of the belt, and then provide the patient with the following instructions:

   – Keep your body straight and head up.

   – Walk in a normal walking position with arms at your sides, or place your hands lightly on the handrails for stability but do not bear down with too much gripping force.

   – Use as little upper-body motion as possible and stay near the front of the treadmill.

You are now ready to begin the Exercise phase.

To begin the Exercise phase

▶ Click the **Exercise** button on the Procedure bar.

The **Exercise** screen is displayed.

Exercise Phase

At the start of an exercise stress test, CAlg has a “Learning Phase” where it automatically selects the initial 12-lead dominant QRS complex. CAlg removes baseline wander and aligns successive non-noisy complexes of similar shape and then averages them together to form a noise-reduced representative beat. As new, similar complexes arrive, they are added to the representative beat, and old complexes are removed from it. When CAlg stops finding good matches for the representative beat and all old complexes have been removed, it will automatically detect a new dominant morphology and build a new representative beat. CAlg makes ST measurements on the noise-reduced representative beat.

During the test, you can print 12-lead ECGs automatically or manually. You can choose any of the following display choices:

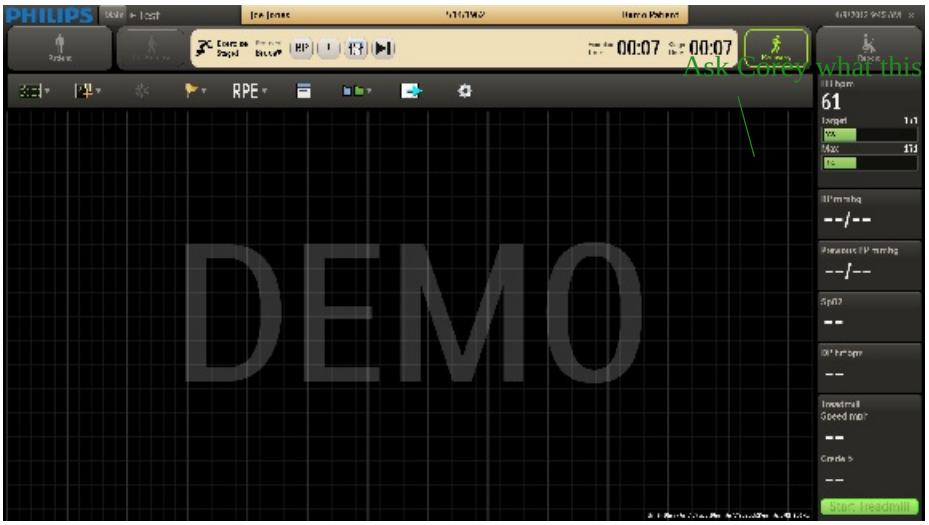
- 12 leads
- 6x2 leads
- 6 leads
- 3 leads

You can start the **Exercise** phase of the test at any time; however, a warning message will be popped up if not all 12 leads ST value is gotten from the algorithm.

Conducting the Exercise Stress Test

When you move into the Exercise phase of the test, the treadmill loads the settings associated with the first stage of the test, and the stage and phase clocks start counting.

Figure 3-10 Exercise Screen



Ask Corey what this means...

The exercise time builds cumulatively as the patient completes each stage. However, with each new stage, the stage clock restarts at 00:00. The stage time, speed, and elevation for each stage are defined by the protocol.

If you want to move to the next stage, without waiting for the system to automatically change, you can click the **Advance** button on the Procedure bar. This starts a new stage and a new stage time, but the exercise time continues to build.

If the patient can no longer continue exercising, you can end the **Exercise** phase of the stress test by selecting **Recovery** (or by pressing the **Stop Treadmill** button if necessary)**.** The Recovery phase is preset to slow down the treadmill and lower the elevation.

Monitoring the Patient

During the Exercise phase:

- The patient walks on the treadmill or peddles the ergometer, unless the patient is unable to exercise or is not using an exercise device.
- You record blood pressure, observe events, and record RPE, while closely monitoring the patient.
- You can switch from an automated protocol to manual operation, giving you full control over the treadmill. To switch to manual control, see “Controlling the Treadmill or Ergometer” on page 3-35.
- You can change the display parameters, as needed during the Exercise phase. For details, see “Using the Toolbar Icons” on page 2-15.
- The Exercise phase comprises several stages, which are defined by the selected protocol. For a breakdown, see Appendix B, “Protocol Reference”.

Figure 3-11 Exercise Stage and Protocol

In general, you will most likely use the standard settings as specified by the profile and protocol selected.

Changing to Another Protocol

If you need to switch to a different protocol at any time during the Exercise phase of the test, use the drop-down arrow by the current protocol to select a new protocol. The phases and stage settings associated with the newly selected protocol are loaded into ST80i.

See the *ST80i Installation and Configuration Guide* for setting default protocols.

To change to another protocol

1 Click the drop-down arrow by the current protocol shown in the Procedure Bar.

Figure 3-12 Protocol Drop-Down List

2 Select the new protocol from the list

The time on the clock resets to 00:00 for the next stage.

When you change the protocol, the test advances to the selected protocol, starting at the beginning of the next stage. Both the speed and grade settings change to reflect the new protocol.

NOTE You can also switch back to the previous protocol. When you do this, a new stage appears in the Procedure Bar and the time clock adjusts back to 00:00.

Rhythm Print

You can print a continuous rhythm strip directly from the ST80i screen at any point during the test. The system generates a continuous report (configurable from 1 to 12 leads) of the leads specified in the configuration for the particular profile. For details, see the *ST80i Installation and Configuration Guide*.

The continuous rhythm strip contains the patient's name and the current date and time. You can generate continuous rhythm strips during all phases of a test.

Any scheduled automatic 12-lead or manually generated events that occur during continuous rhythm printing are saved for later review or printing and are included in the final report.

To change the settings for Rhythm Printing before printing the Rhythm Strip

1 Use the **Page** icon to set the top of the page

2 Use the **Gear/Quick Settings** icon [Gear/Quick Settings → Rhythm Print] to set the Leads, Limb Gain, Chest Gain, and Speed.

To print a continuous strip

1 Click the **Rhythm Print** icon.

A continuous Rhythm Strip will print.

2 Click the **Rhythm Print** icon again to stop the strip from printing.

12-Leads Print

The timed printing of the 12-Lead ECG is based on the Exercise Protocol settings that are preconfigured on the Config screen's Exercise Protocol tab. For details, see the *ST80i Installation and Configuration Guide*.

In addition to the timed printing of an ECG, you can also generate 12-lead ECGs during all phases of the test. Select this icon if you want to print a 12-lead ECG in real time.

NOTE 12-Lead ECG also prints when an Event or RPE is recorded. The ECG also includes pacemaker detection as well as arrhythmia notification, if enabled.

To print a real-time 12-Lead ECG

▶ Click the **12-Leads Print** icon.

A 12-Lead ECG will print.

Controlling the Treadmill or Ergometer

At any point during the stress test, you can switch to “Manual Mode” and change the speed and elevation grade of the treadmill. This overrides the protocol settings for the current stage. Once you enter manual mode, there is no next stage.

CAUTION Be sure to inform the patient of the changes.

If the treadmill is unavailable, ST80i displays “Unavailable” where the **Start Treadmill** button would be.

To change the speed and elevation of the treadmill

1 Place the pointer in the field that shows the current speed and click.

A box with a minus (-) sign to the left and a plus (+) sign to the right of the current setting is displayed.

Figure 3-13 Treadmill Spped and Grade Adjustment

2 Make the appropriate adjustment, down or up, and click **OK**.

3 Place your pointer in the field that shows the current elevation and click.

A box with a minus (-) sign to the left and a plus (+) sign to the right of the current setting is displayed.

4 Make the appropriate adjustments, down or up, and click **OK**.

Figure 3-14 “Manual Mode” pop-up warning

To stop the treadmill during the Exercise phase

▶ Click the **Stop Treadmill** button.

The Treadmill stops.

Consult “Maintaining the ST80i System” on page 5-1 with regard to the inspection of cables and attachments between the PC and the Treadmill.

Notifications and Alerts

ST80i provides visual indications or alerts in case of dramatic morphology or rhythm changes. All notifications are preconfigured in the user profile. They include the fields to be displayed or printed as well as specific audio alerts.

As part of the user profile, you can select to display and/or print the following Arrhythmia fields:

- Asystole [SRS 3.2.14.3.14]
- Absolute Pause
- 1 missing beat
- 2 missing beats
- Ventricular Fibrillation
- VT
- SVT
- Premature Ventricular Contractions (PVC)
- Extreme HR
- Sudden drop in BP
- Vrun(>=3PVs)
- Vcouplet(2 PVCs)
- Ventricular Bigeminy
- Ventricular Escape Beats
- Afib

The preconfigured audio alerts consist of the following:

- NIBP
- SpO_2
- Dose
- Notifications

- Stage Change

See the *ST80i Installation and Configuration Guide* for more information regarding the setting of notifications.

See also “Global Interpretive Settings” on page 3-40.

Ending the Exercise Phase

The protocol determines the number of exercise stages as well as their duration. Once the final stage is complete, the application automatically moves into the Recovery phase.

During the final stage, you can end the exercise stress test and move directly to Recovery by clicking the **Advance** button on the Procedure bar.

Generally, you terminate the Exercise phase when the patient reaches a percentage of their target heart rate. The clinician determines the end point according to patient's status and many patients never reach 100%. The target heart rate is pre-configured in the user profile.

If the reading reaches 100% of the target heart rate, the graph indicator color changes from aqua to red.

Recovery Phase

When the last stage of the Exercise phase is complete, ST80i automatically moves into the Recovery phase. The Recovery phase is preset under Exercise Protocols to run for 3 minutes at a maximum speed of 1.5 mph with an elevation of 0%.

See the *ST80i Installation and Configuration Guide* for Exercise Protocol settings.

When the patient has completed the Exercise phase or the test has been discontinued (as documented in “Reason to End” in the Summary), the exercise stress test enters the Recovery phase.

To automatically enter the Recovery phase

- If the last exercise stage of the protocol is completed, ST80i automatically enters the Recovery phase.

To manually enter the Recovery phase

- Click **Recovery.**

  The system moves into the Recovery phase of the test.

You can now acquire a resting ECG and blood pressure and proceed with the Recovery phase of the test.

During the Recovery phase:

- The system automatically prints a 12-lead ECG. The 12-lead ECG is printed at this stage transition regardless of system settings.
- The total exercise time clock freezes.
- ST80i advances the treadmill or ergometer to the recovery workloads specified in the protocol.
- Select **Stop Treadmill** to stop the Treadmill. (You can also select the **End** button)
- Using the Notes icon, you can enter comments describing why the patient ended the **Exercise** phase of the test, the patient's symptoms, and conclusions.

Figure 3-15 Recovery Phase Screen

To end the Recovery phase

1. Click the **Report** button.

   A message displays: "Confirm End of Study. The data will be saved."

2. Click **OK**. You also have the option to cancel.

   The message "Loading" is displayed.

   The Report screen is displayed.

Report Phase

When you have determined that the patient has completed the Recovery phase of the stress test, you can manually move to the Report phase where the Report screen is visible.

Data from the Recovery Phase is saved as part of the Final Stress Report. When you save the stress test, the patient enters the Post-Recovery phase. This phase appears as part of the Report phase in the Final Stress Report.

Post-Recovery

The Post-Recovery phase begins when the Recovery phase ends, and it stops when the Report screen is opened. The Post-Recovery phase lasts from 5 to 60 minutes. During the Post-Recovery phase, ST80i continues to monitor the ECG, arrhythmia alerts, as well as sudden HR and BP changes. Data will not be saved unless an event is triggered. If events are triggered, the event data is saved as part of the final report.

See “Notifications and Alerts” on page 3-36

NOTE ST80i will stop stream-test data after the 60-minute Post-Recovery phase. From the Report screen, you can review and modify the content of the final test report. You can print the individual reports that are also included in the final report, save the final report, and print it. After you save the report, you can export it to a PDF file for distribution or storage.

Report Screen

On the Report screen, you can review and edit the stress test results to prepare the Final Stress Report. The final report includes the Patient Information, Summary, Trends, Average QRS, Resting ECG results, Events, and Tabular Report. The report is then confirmed, saved, exported, archived, and/or printed on pre-configured printers. You have the option to print the whole report or specify which page(s) to be printed.

From the Report screen, you can also review or replay the stress test and finalize (or confirm) the final report before export.

See “Working with Reports” on page 4-1 for information on the Report Phase and Report screen.

Global Interpretive Settings

In the Settings section of the ST80i application, you can configure the Global Interpretive Settings for DXL Algorithm and CALg templates, include the following:

DXL Algorithm

- Adult Bradycardia
- Borderline Statement Sensitivity
- Pacer Detection
- Report Confirmation Label

CALg Templates

- Arrhythmia Analysis
- ST Segment Analysis
- J-ST Settings

Global Interpretive Settings also include:

- Arrhythmia Event Notification
- ST Amplitude Calculation

To configure the Global Interpretive Settings, see the *ST80i Installation and Configuration Guide*.

Pace-Pulse Detection

The Pace-Pulse detection algorithm detects both atrial and ventricular pacing. Pacemaker detection is preset in the user profile. The options include:

- Paced
- Paced (Magnet)
- Non-Paced
- Not Known if Paced

  "Not known if paced" is the default mode, in which the detector uses its default sensitivity setting to determine if pacemaker pulses are present.

The pace-pulse detection setting in effect at the time a snapshot is taken is used for the analysis of that snapshot. If the pace-pulse program is enabled and it detects the presence of pace-pulses, it will provide output in textual and graphical formats:

- The interpretive report will contain textual statements about the findings for the pace-pulse program.

- Tick marks appear on the waveform (both printed and displayed) at locations where pulses are detected. The interpretive report contains textual statements about findings.
- Only one set of tick marks will be printed for any given period of acquisition, regardless of the number of channels presented.
- The pace-pulse detection setting, in effect at the time a snapshot is taken, is used for the analysis of that snapshot.

To configure Pace Detection, see the *ST80i Installation and Configuration Guide*.

Printing During the Stress Test

At any time during the stress test, you can trigger real-time ECG (a real-time ECG is defined as 10 seconds of ECG data) and continuous Rhythm printing using the icons displayed on the Exercise screen. The time latency should be less than 7 seconds. You can also capture and store events for later review and reporting. The events can be saved with notes and can be printed with the context ECG data.

Arrhythmia events can trigger automatic printing with the context ECG, if configured. In addition, you can also turn off the continuous printing both on the configuration and during the test.

Printer Configuration

During the patient session, you have two print options:

- ECG Print
- Rhythm Print

Some print settings are preconfigured in advance while some can be changed during an exercise stress test. The settings include:

- Printer selection
- Timing of Print
  - ECG Print - by stage
  - ECG manual - using the ECG Print button
  - Rhythm Print manual - using the Rhythm Print button
- Print layout

On the Config screen [System Settings → System], you can preconfigure the printer for each type of report:

- Select ECG Report Printer:
  - Off
  - PDF Complete
  - Microsoft XPS Document Writer
  - Local Thermal Printer
- Select Event Report Printer:
  - Off
  - PDF Complete
  - Microsoft XPS Document Writer

  - Local Thermal Printer
- Select Rhythm Report Printer:
  - Off
  - Local Thermal Printer
- Select Final Report Printer:
  - Off
  - PDF Complete
  - Microsoft XPS Document Writer
  - Local Thermal Printer

On the Config screen [User Profile → ECG Report], ECG Print is preconfigured with the following:

- ECG Layout
- Speed (mm/sec)
- Gain (Limb Leads)
- Scale (Chest Leads)

On the Config screen, the timing of the ECG Print is configured on the Exercise Protocols tab. The print interval options include:

- Off
- Begin
- End
- EveryLeads

You can also print an ECG at any time by clicking the **12 Leads Print** button.

On the Config screen [User Profile → Rhythm Report], you can configure Rhythm Print settings for the Rhythm Report. They include:

- ECG Layout - select Leads
- Rhythm Settings
  - Speed mm/sec - 5, 10, 25, 50
  - Gain (Limb Leads) - 2.5, 5, 10, 20
  - Scale (Chest Leads) - Full, Half

During the patient session, you can change the Rhythm Print settings using the **Gear (Quick Settings)** icon. See “Using the Toolbar Icons” on page 2-15 for an explanation.

Print Options

ST80i supports several print options during the stress test, including:

- Real-time ECG
- Resting 12-Lead ECG report (with interpretation) – interpretion is printed only during Pre Exercise phase when an event is selected
- Stage printout (without interpretation)
- Event printout (without interpretation)
- Real-time rhythm printing

Real-Time ECG

Any time during the testing, you can print a real-time 12-Lead ECG from the Exercise screen.

You can trigger a real-time ECG using the **12 Lead Print** button on the screen. The time latency should be less than 7 seconds.

To print a real-time ECG

▶ Click the **12 Lead Print** button on the Procedure bar.

12-Lead Resting ECG Report

Before the formal stress testing starts, or after the stress testing completes, you can print a 12-Lead resting ECG report.

The 12-Lead Resting ECG is printed according to the user profile settings. Resting ECG measurement and interpretation is included as part of a 12-Lead ECG Report.

- Report Title
- Patient Demographic
- Study Information
- Interpretation of 12-Lead ECG statement
- 12x1, 6x2, 3x4, 3x4 3R display

To print a 12-Lead Resting ECG Report

▶ Click the **12 Leads Print** button on the Procedure bar.

For more information on printing reports, see “Working with Reports” on page 4-1.

Stage Printout and Event Printout

Stage printout and Event printout are 12-Lead ECG reports without any measurement or interpretation during the stress testing. Stage printout is configured in the Protocol. Event printout is printed if the printer type is configured.

- The Stage printout is automatically generated if preconfigured. It prints out an average report of the stage, which shows the average beat maximum ST changes in this stage as well as the current ST change. This is defined for each stage of the exercise protocol when an ECG is automatically generated for the stage.
- The Event printout is triggered when you document patient symptoms using the **Event** icon.
  - Event symptoms include: Supine, Chest Pain, Shortness of Breath, Mason-Likar, Standing, and Hyperventilation.
  - You can also document a new event using this icon.

NOTE If enabled, Arrhythmia events can trigger automatic printing with the context ECG – which are configurable to the user.

See the *ST80i Installation and Configuration Guide* for how to enable Arrhythmia events.

At the end of each stage, ST80i automatically prints an average report of this stage. This report shows the average beat, maximum ST changes in this stage, as well as the current ST change.

You can also print at any time during the test from the Exercise screen to capture and store events or snapshots for later review and reporting. The followingevents and snapshots can be saved with notes:

- Hyperventilation
- Chest Pain
- Shortness of Breath
- User-defined urgent case

To record and print an Event, see “Recording an Event” on page 2-25.

The Stage/Event printout includes the following:

- Report title
- Protocol name, phase, stage number, etc.
- Patient demographic
- Heart rate, blood pressure, MPH, etc.
- ECG Waveform
- Average beat
- Event name (for Event printout only)

- Maximum ST changes in this stage (for Stage printout only)
- Current ST change (for Stage printout only)

Continuous Rhythm Strip

You can trigger continuous rhythm printing using the **Rhythm Print** button on the Exercise screen. You can also turn off continuous printing by using the same **Rhythm Print** button.

Before using the Rhythm Print option, you can:

- ST80i software automatically advances the paper to the page header
- You can adjust Rhythm Print settings using the **Gear (Quick Settings)** icon

To print a continuous Rhythm Strip

1. Click the **Gear (Quick Settings)** icon; select the Rhythm Print tab.
2. Adjust the settings, if applicable, for:
   - Leads (Select the leads you want to print)
   - Limb Gain (options include: 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV)
   - Chest Gain (options include Full, Half)
   - Speed (options include 5 mm/s, 10 mm/s, 25 mm/s, 50 mm/s)

3. Click the **Rhythm Print** icon
4. To end the printing, click the **Rhythm Print** icon again.

De-Identification

When printing patient reports, you can de-identify the study to be in HIPAA compliance. This option hides all patient identification information from the study printout so that the identity of the patient is protected.

This option is preconfigured in the Settings section of the application.

To de-identify a patient

1. Click **Settings** on the Main Screen.
2. Select the System Settings tab
3. Select the System option
4. Place a checkmark in the “De-identify Patient Information on Report” box
5. Click **Save**.

Proceed to “Ending the Patient Session,” which follows.

Ending the Patient Session

After saving the Final Stress Report, you are ready to close out the patient session.

The patient can now be disconnected from the PIM:

- Detach patient from PIM.
- Detach electrodes.

For details about working with the final report, including viewing, editing, printing, and saving reports, see “Working with Reports” on page 4-1.

Starting a New Patient Session

You do not have to exit the application to start a new session, unless you want to use a different user profile. Otherwise, you exit the application only when you are shutting down the system.

Once the data from the previous patient session has been saved, you can begin a new patient session. All user profile settings will return to the same as the previous test unless the application is exited and a different user logs in. Some of the settings changed using the **Gear (Quick Settings)** icon also remain in effect.

NOTE All patient information and stress study data of the previous patient is cleared automatically when a new patient session starts.

To start a new patient session

1. Select Main.
2. Select Worklist.
3. Select the patient’s name.

Exiting the Application

You exit the application when need to use a different profile, when a new user is logging onto the system, or when you are shutting down the system.

To exit the ST80i application

- Click the “X” in the upper right corner of the Main screen.

4

Working with Reports

Overview

When you enter the Report phase, data from all phases of the test are saved as part of the final stress report that is viewed on the Report screen.

From the Report screen, you can review and modify the contents of the Final Stress Report, which is displayed in tab format. This includes report summary information, trends, average QRS, events and resting ECG. You can save the final report, and then print it. In addition, you can print the individual reports that are part of the final report. After you save the report, you can export it as a PDF file for distribution or storage.

This chapter provides the following information:

Report Phase

When stress testing enters the Report phase, you can edit the report with the algorithm output to generate a Final Stress Report. The final report is divided into several pages that include, for example, the report summary, trends, average QRS, events, and resting ECG.

During the Report phase:

- ST80i freezes the Recovery display while the test information is transferred to system storage.
- ST80i loads the Report screen, so you can specify the parameters and format of the final report.
- A real-time 7.5-second ECG is displayed in the lower-left section of the screen for the Post-Recovery phase

Post-Recovery Phase

A Post-Recovery phase lasts from 5 to 60 minutes. During the Post-Recovery phase, ST80i will continue to monitor the ECG, arrhythmia alerts, as well as sudden HR changes. Data will not be saved unless an event is triggered. If events are triggered, the event data is saved as part of the Final Stress Report.

NOTE ST80i will stop streaming test data after the 60-minutes Post-Recovery phase.

Report Screen

During the Report phase of the test, you work from the Report screen to review, update, and save the data for the Final Stress Report, which you can then save, confirm, export, archive and/or print on pre-configured printers. You have the option to print the whole report or specify which individual reports to print and to change default printer settings.

From the Report screen, you can also review or replay the exercise stress test and finalize (or confirm) the final report before export.

As you prepare the final report on the Report screen, you can do the following:

- Review the ECG and make any adjustments to the waveforms (for example, to the J-point, if needed)
- Add or update patient information
- Print the individual ECGs and delete extraneous ECGs
- Review and edit final test data
- Review events
- Review the exam
- Prepare the patient's final stress report
- Save the report and export it, if appropriate
- Archive the patient's stress report

The Archive screen is used to store the exercise stress test results. All reports and test records are stored in ST80i and are exported to servers based on settings.

Changes made to the Final Stress Report through ECGVue are saved into the database where the ECGVue is connected.

NOTE The Final Stress Report is also stored in the stress system's Report database, which you can access on the Main screen. When you click the **Report** button, the "Select Archive from List" screen is displayed. Each report is labeled according to its status:

- Complete: all required fields are filled
- Incomplete: any required field is not filled
- Confirmed/Signed
- Exported

For more information regarding archived reports, see "Working with Archived Reports" on page 4-36.

Figure 4-1 ST80i Report Screen

Table 4-1 ST80i Report Screen Features

Feature	Description
A	Title Bar - where you enter or update patient information in the Patient Demographics window.
B	Procedure Bar - [Report, Status: Complete or Incomplete] and buttons: **Change J+ , Save, Export, Print, Confirm, Replay**
C	Report Tabs → Summary, Tabular, Trend Graph, Averages, Events, Resting ECG, Full Disclose
D	Real-time 7.5-second ECG by selected lead (ECG for one lead is displayed in the lower left section of the screen; use the Change Lead drop-down arrow to change selected lead)
E	Two print options for the current ECG lead: Print 12-Lead ECG Report; Start Rhythm Printing
F	Current Blood Pressure – shows current blood pressure of the patient

Title Bar

From the Report screen, you can enter or update information about the patient before or during the test. If you did not fill in or update this information during the Exercise phase, you can open the Patient Demographics screen to update this information as necessary. For an explanation of the features of the title bar, see “Title Bar” on page 2-7.

When you click the patient’s name on the Title Bar, you can update or amend the following information:

- Patient Information
- History
- Medications/Dosage
- Physician/Order
- Custom Fields

To add or update patient information

1. Click on the Patient Name in the Report screen title bar.

   The system displays the Patient Demographics window.

2. Enter new information for the patient or update the fields as needed.

   For details on the fields in the window, see “Patient Information Management” on page 3-5.

3. Click **OK** when finished to save the data.

If you manually update patient information, including Notes and Symptoms during the test or on the Report screen, this information is updated in the archived report in the Report stress system database.

Procedure Bar

Figure 4-2 Procedure Bar

On the Procedure bar, you can:

- Adjust the J+ Point
- Save the report
- Export the report
- Print the report
- Confirm the report
- Replay the ECG

Change (J+) Point

The ST Measurement (J+) Point is preconfigured in the user profile.
[Settings → User Profile: Algorithm → J-ST (msec)]

You can adjust the J+ Point value on the Report screen to re-analyze the stress test using a different measurement point. Once the J+ms value is modified, ST80i recalculates all related values and updates the corresponding displays on the Report screen.

NOTE The new ST value does not automatically replace the old one until the report is saved.

To modify the ST measurement point

▶ On the Procedure bar, click the plus (+) or minus (-) to change the value in milliseconds for J-ST.

To recalculate all the ST values based on the new J+ setting

▶ Click the **Change J+** button.

Save

Use this button to save the report to the stress system database after you have finished updating and reviewing the report data.

When a Final Stress Report is saved, it may then be exported to the central server. The report can be finalized and signed on both device side and server side. The stress study raw data will be saved in the local stress study database. The export status and date/time of last export are also maintained.

It is also possible to export a report [directly to external media such as a USB flash stick in PDF format. The Final Stress Report may also be exported in PDF format which can be reviewed on any PC. The Final Stress Report in PDF format can then be emailed to referring physician. See also “Exporting Reports (Export Exam)” on page 4-44.

Export

You can export your reports to Remote Sites that have been preconfigured in the Settings section of the application.

If you have not configured Remote Sites, you will get the following error message: “Error. No default remote site is set. Please set default remote site in System Settings!”

To create Remote Sites, see the *ST80i Installation and Configuration Guide.*

See also the section regarding the export of archived reports entitled “Exporting Reports (Export Exam)” on page 4-44.

To export a report using the Export button -- *procedure in development*--

Print

You can use the Procedure bar's **Print** button to print individual reports or the Final Stress Report.

Before printing individual reports, you need to select a printer type. When using a laser printer, the grid can be set to print a grid on standard paper. Individual reports can be printed both before and after you save the report.

The type of individual reports that can be printed include:

- Patient ID
- Summary
- Trend Graphs
- Average QRS
- 12-Lead Resting ECGs
- Rhythm Events

When printing a Final Stress Report, you can choose which individual reports to include and the number of copies to print for each individual report. You can also print a complete Final Stress Report. Regardless of settings, a summary report will always be printed on the first page of a Final Stress Report.

See the section entitled "De-Identify the Report" on page 4-35 regarding how to print individual reports as well as the Final Stress Report.

Confirm

Once you review and edit the results, you can then confirm the report before exporting. You will, however, need the appropriate permission level to export the report.

In the Select Archive from List window, the test status is listed as follows:

- Complete: all required fields are filled
- Incomplete: any required field is not filled
- Confirmed/Signed
- Exported

NOTE A stress study report cannot be confirmed or exported to TMVue if the required patient fields are not complete.

For more information regarding patient fields, see the section entitled “Patient Information Management” on page 3-5.

When you click the **Confirm** button, a dialog box is displayed.

Figure 4-3

To confirm the report

1. Enter your User ID.
2. Enter your password.
3. Click **OK.**

Replay

When you click the **Replay** button on the Report screen, you can review the real-time ECG waveforms. This button provides you with the ability to review a back-completed stress report that is either finalized or non-finalized.

You can also print a 12-Lead ECG or print a rhythm strip during the review of the study. This feature is beneficial if you wish to review a specific segment of the test. When reviewing a test, you can:

- Change the ECG waveform speed from real-time speed to four times faster or slower
- Pause the ECG stream
- Print or reprint a 12-lead ECG or rhythm strip for significant episodes
- Move the trend cursor to any location to skip forward or back in time

To replay the exercise stress test

1. Click the **Replay** button on the Procedure bar.

   This brings you to ECG results that were recorded at the start of the Exercise phase. You can then view the exercise stress test by using the “floating status bar” that appears at the bottom of the ECG. This bar may be hidden.

2. To view the bar, sweep your pointer over image.

   A gray circle moves across the status bar (blue). As it moves, the time is displayed to the right showing both current and end time.

Figure 4-4

Figure 4-5

3 To hide the bar, sweep your pointer over the image.

At any time during the Replay of the exercise stress test, you can print an ECG or Rhythm Strip.

- Click the **ECG** button for a 12-Lead ECG.
- Click the **Rhythm Print** button for a rhythm strip.

Once you have replayed the ECG, you can return to the Report screen.

To return to the *Report* phase screen -- *procedure in development--*

NOTE Once the patient session is over, you can also review a patient test, after you have saved the results, by going to the Main screen. Click the **Report** button to open the Select Archive from List screen. See the section entitled “Working with Archived Reports” on page 4-36.

Real-Time ECG for One Lead

On the bottom of the Report screen, patient data is still captured for one lead. You can change the lead by using the drop-down menu to the right.

Figure 4-6

Print Options

On the bottom of the screen, to the right of the real-time ECG, are two print options for the current lead in view:

- Print 12-Lead ECG Report
- Start Rhythm Printing

When you click the **Print 12-Lead ECG Report** button, you will get a printout of that segment of the ECG.

When you click the **Start Rhythm Printing** button, a rhythm strip begins printing. To turn off Rhythm Printing, click this button again.

Current Heart Rate

The current heart rateof the patient is displayed on the bottom right section of the screen.

Final Stress Report Overview

The Final Stress Report is based on data gathering during the 5 phases of an exercise stress test. They include:

- Pre Exercise Phase
- Exercise Phase
- Recovery (and Post-Recovery) Phase
- Report Phase

The Final Stress Report includes the patient information summary, trends, average QRS, resting ECG results and events. ST80i allows you to choose several individual reports to include in the Final Stress Report.

The composition of a stress report may or may not include the following:

- Patient ID Report
- Summary Report
- Trends Report
- Average QRS Report
- 12-Lead ECG Report
- Rhythm Events Report
- ST Analysis
- Interpretation
- Measurements

After finishing the data acquisition, stress testing enters the report-generating phase. Once signed by a cardiologist or clinician, the report is finalized.

After a stress test procedure, you work from the Report screen to review, update, and save the data for the Final Stress Report. When the report is satisfactory, you can print the individual reports on a laser printer or directly to a thermal printer when printing from ST80i.

Data from the Recovery phase is included as part of the final report. In the Post-Recovery phase, the data will not be saved unless an event is triggered. If so, only the event data is saved as part of the final report.

WARNING ECG signals printed on a laser report should not be used to make time-sensitive measurements directly from the printed page.

NOTE The Final Stress Report cannot be saved without patient demographics.

A Final Stress Report includes the following:

- Patient ID
- Summary
- Tabular Summary
- Trends Graph
- Average Beat Complexes
- Rhythm Events
- 12-Lead Interpretative Resting ECG Report

Each report is configured to print or not to print in a Final Stress Report except thePatient ID Report, which is the minimum printed page in a Final Stress Report. It is printed as the first page of the Final Stress Report.

You can configure which reports are included in the Final Stress Report. This setting can be changed from the Report screen.

- Patient ID Report
- Summary Report
- Trends Report
- Average QRS Report
- Rhythm Events Report
- 12-Lead ECG Report

You can reprint each report manually. You can also specify the number of final report copies to print. In addition, you can specify the printer to send the final report copies and whether or not to have the grid visible.

CAUTION If you input incorrect NIBP data, it can cause errors for NIBP-related parameters in reports.

Report Screen Tabs

The sections of the final report are displayed as tabs on the Report screen. The tabs contain the patient's ECG data in a variety of formats:

- Summary
- Tabular
- Trend Graphs
- Averages
- Events
- Resting ECG
- Full Disclosure

Figure 4-7 Report Screen

The following sections describe each report tab:

Summary Report

The Summary Report includes:

- Report title and patient demographics
- Study information including, for example, study date and time, test type, protocol, referring physician, attending physician, and technician
- Clinical information including, for example, the reason for the test and the reason to end test, PVCs, Risk scores, test summary for all phases, free-text entry of narrative summary notes, and signatures

On this screen, the gender specific parameters, measurements and risk scores that are displayed can be printed. In addition, you can override the algorithm and select Max ST deviation for the risk-score calculation. When you change the parameters, they appear in dark red and italic.

NOTE The Summary Report cannot be printed without patient demographics.

On the Summary tab of the Report screen, you can include your comments about the test, along with the Reason to End and Symptoms. All values included are based on data captured during each stage of the exercise stress test. The screen is divided into four sections:

- Summary – The Summary region shows total exercise time, maximum treadmill speed, and maximum grade or watts (for Ergometers), as well as leads displaying greater than 100 microvolts of ST change. Duke and FAI score also appear, if applicable. FAI % statistics only appears for the Bruce protocol.
- Max Values – Max values are presented as HR and time-achieved percentage of target HR achieved, and maximum METS obtained as well as Double Product and maximum systolic BP/maximum diastolic BP.
- Max ST – Maximum ST measurements, based on J+60ms, are presented with elevation, depression, total change, and ST/HR Index.
- Comments – In the Comments section, you can:
  - Update the Comment fields:
    - Narrative
    - Technician
    - Reviewing Physician
    - Reason for End – Update the Reason for End using the up and down arrows, as well as the **Del** and **Add** buttons.

      The ComboBoxItem 1 below Reason for End is used for X.
    - Symptoms – Update the Symptoms using the up and down arrows, as well as the **Del** and **Add** buttons.

      The ComboBoxItem 1 below Symptoms is used for Y.

The Summary Report includes the following information on page 1:

- Summary data displayed on the Report screen:
  - Total exercise time
  - Maximum treadmill (or ergometer) speed and grade achieved during test
  - Max grade
  - ECG leads that presented more than 100 uV (or 1 mm) of ST elevation or depression during test
  - Functional Aerobic Impairment (FAI%). Only for Bruce protocol
  - PVCs

  - Duke Score (treadmill only)

- Max Values data displayed on the Report screen:
  - Maximum heart rate
  - Percentage of target heart rate attained
  - Estimated maximum metabolic equivalents (METS)
  - Double Product (Sys HR * BP)
  - Maximum systolic and diastolic blood pressure

NOTE These values are not necessarily taken from the same blood pressure reading. They are simply the highest measurements recorded of each of these values at any time during the test.

- Max ST data displayed on the Report screen:
  - Absolute ST Elevation and ST Depression times and leads
  - Amount of ST Elevation and ST Depression change
  - ST/HR Index

NOTE Patients may already have ST elevation or depression before exercise begins. It is important for the clinician to see how much change occurs during exercise.

To print the Summary Report ***-- procedure in development--***

Tabular Report

The Tabular Report includes:

- Report title and patient demographic data
- Study information including study date and time, ST measurement, test type, protocol, referring physician, attending physician, and technician
- Table items configurable per stage, phase name, stage name, relevant stress-related data, and a time stamp of events

The Tabular tab displays the following tabular data by Exercise stage or by minute:

- Time
- Speed
- Grade
- HR

- BP
- METS
- HR*BP (Double Product)
- 12 Leads

Figure 4-8 Tabular Data Displayed by Stage

To print the Tabular Report ***-- procedure in development--***

Trend Graph Report

The Trend Graph Report includes the following:

- Report title and patient demographic data
- Study information including data and time, test type, and protocol
- 4-Graph Trends (measurements vs. minutes)
- ST Level Trends (mms vs. minute)
- Test protocol

The following graphs are displayed:

- Heart Rate
- Blood Pressure (Systolic and Diastolic)
- Speed/Grade of the Treadmill (or data from the Ergometer)

- METS/Double Product (HR*BP)
- Trends by lead for ST Level and ST Slope (use the right and left arrows to scroll)

To review the leads to the right, use the scroll bar.

Figure 4-9 Trend Graphs

To print the Trends Report ***-- procedure in development--***

Averages Report

The Average Beat Complexes Report is an overview of median morphologies by stage or by minute that are configurable at pre- and/or post-test stages.

This report includes:

- Report title and patient demographic data
- Study information
- Default median morphologies for 12-lead at baseline, Max ST Depression, Peak Exercise and End Test
- User-defined median morphologies for 3, 6, and 12 leads at user-defined intervals as well as ST Level and ST Slope for each lead

You can use the **Print (Quick Print Settings)** button to print the report by stage or by minute.

Events Report

You can review Rhythm Events at any time after you enter the Report screen by clicking the Events tab. You can also delete events that you do not want to include in the Final Stress Report, and re-label events more appropriately.

The Rhythm Events Report includes prints of snapshots of all events, captured arrhythmias, and RPE scale selections acquired during the Stress test. In addition, an Event Report is configured to print each time during the exercise stress test if a specific event (e.g. Shortness of Breath, Chest Pain, etc) was selected from the drop-down menu using the Event icon.

12-Lead ECGs that are printed during the Exercise and Recovery phases are included with the Rhythm Events Report.

The Rhythm Events Report includes:

- Report Title
- Protocol Information
- Patient Demographic Data
- Heart Rate, Blood Pressure, MPH, etc.
- ECG Waveform
- Average Beat
- Event Name (for Event printout only)

Figure 4-10 Events Tab

On this tab, you can:

- Review Rhythm Events for all captured events (e.g. Chest Pain, Hyper Ventilation, Shortness of Breath, Ventricular Tachycardia, Bigeminy, Trigeminy, etc.), arrhythmias, and RPE scale selections acquired during the entire stress test.
- Review 12-Lead ECGs printed during the Exercise and Recovery phases that are included

with the Rhythm Events.

- Print and delete Rhythm Events as well as re-label them, as appropriate. Use the **Print (Quick Print Settings)** button to print the events.

You can also review all the events captured during the test. In addition, you can also create new events during the review. The newly captured events are added to the final report and then saved back to the database.

To review Rhythm Events

1 Click the Events tab.

The Rhythm Events window appears, displaying up to six events. Use the right and left arrows to scroll.

2 To select an Event, click anywhere in the Event snapshot to highlight it.

3 Review the Event. You can perform any of the following actions:

- Click **Print** on the Procedure bar screen to print the Event.
- Click **ReLabel** to re-label an event.
- Click the "X" in the upper right corner of each Event to delete the Event. The word Deleted appears across the Event in red. All deleted events are removed from the list.
- Click **OK** when finished to save your changes.

To re-label Events -- *procedure in development--*

1 Click the Events tab.

The Rhythm Events window displays up to six events. Use the right and left arrows to scroll.

2 To select an Event to re-label, click anywhere in the Event snapshot to highlight it.

To delete Events -- *procedure in development--*

1 Click the Events tab.

The Rhythm Events window displays up to six events. Use the right and left arrows to scroll.

2 To select an Event to delete, click anywhere in the Event snapshot to highlight it.

To print Events -- *procedure in development--*

1 Click the Events tab.

The Rhythm Events window displays up to six events. Use the right and left arrows to scroll.

2 To select an Event, click anywhere in the Event snapshot to highlight it.

IMPORTANT! Rhythm change notifications are provided when specific rhythm changes are detected; however, it is the responsibility of the trained healthcare professional to determine the type of rhythm change and appropriate action.

Additionally, the healthcare professional should not assume that all rhythm changes will be detected and they are responsible for taking action when rhythm changes are observed on the displayed waveforms and system fails to provide a notification. It is expected that only properly trained health care professionals working directly under the supervision of a qualified physician will be operating the ST80i Stress Test System during testing.

Resting ECG Report

Resting ECG measurement and interpretation are included as part of a 12-Lead ECG Report. The 12-Lead ECG is printed according to the user profile settings. A Resting ECG is printed at the beginning of each exercise stress test and is then printed in the Final Stress Report.

The Resting ECG tab shows a report of the resting ECG. At the top part of the report, patient data as well as ECG data appears with interpretation. Before the formal stress testing starts, or after the stress testing is complete, you can print a 12-Lead Resting ECG report.

The waveform area captures the ECG during the resting or supine stage during the Pre-Exercise phase. The report is labeled “Supine” or “Mason-Likar.”

The report includes:

- Patient Demographic Data
- Study Information
- Interpretation of 12-Lead ECG Report
- 12x1, 6x2, 3x4, 3x4 3R display

CAUTION Specific patient data is required for each interpretation. If entered data are found to be incorrect, the ECG file may be edited and a new display/report can be printed.

You can configure mandatory patient information fields in system configuration. When these mandatory fields are missing, you will be warned with a pop-up message box. If these fields are changed, a warning message pops up and the resting ECG will be re-interpreted.

On this screen, you can scroll through the images on the screen using the right and left arrows. You can also print a Resting ECG using the **Print** button on the Resting ECG screen.

Full Disclose Report

On this screen, the entire ECG waveform results of the stored stress tests are loaded for full disclosure review.

To view an ECG for the whole exam or a moment in time, use the start feature at the bottom of the screen.

The start time is noted in the bottom right corner of the waveform screen.

To print the Full Disclosure data --- *procedure in development--*

Saving the Final Stress Report

Typically, the Final Stress Report comprises a summary and/or narrative summary page that includes patient name and ID, date of exam, exercise time, maximum HR/ST/BP values, duke score, FAI%, reasons for ending the test, symptoms, conclusions, diagnosis, reviewing physician, and real-time ECG.

The Final Stress Report is created by the reporting application as unsigned or signed (finalized) by a cardiologist or clinician.

When an exercise stress test is complete or the stress test ended for some reason, the raw data and metadata with the accompanying stress report is automatically saved into the local database. Once a stress report is modified and saved, it overwrites the raw data and metadata in the system database. However, the raw data will always be saved into the database as HIPPA compliant.

A stress test is listed on the Archive screen in the stress system database as soon as the test is completed, even if you have not yet saved it. You will see that status listed as “Incomplete” in the Select Archive from List screen by clicking **Report** on the Main screen.

You will also see the status as “Incomplete” on the Procedure bar.

When you finish updating and reviewing the report data, you can save the Final Stress Report to the stress system database.

NOTE The Final Report cannot be saved without patient demographics.

To save the Final Stress Report

- Click the **Save** button (next to the J+ Point modification) on the Procedure bar.

  The stress test contains the pdf report and can be exported. The Report screen is still displayed.

You can now print the final report from the Report screen.

Printing Reports

On the Report screen, there are three options for printing reports:

- **Print (Quick Print Settings) button** - on the Procedure bar
- **Print** button on the Resting ECG tab and Event tab.
- **Post Recovery ECG** (two print buttons below Change Lead at bottom of screen)

The printers, for printing individual reports or the Final Stress Report, are preconfigured in the Settings section of the application. However, the printer default settings and the "Print Grid" on/off setting (if you are using a laser printer) can be changed on the Report screen.

You can also preconfigure the print settings to add your facility logo and site information to the Final Stress Report. See the *ST80i Installation and Configuration Guide* for how to add your facility logo.

The four main reports that comprise the Final Stress Report are preconfigured with specific settings as part of the user profile. This is also done in the Settings section of the application.

- ECG Report
- Event Report
- Rhythm Report
- Final Report

Printer Configuration

ST80i supports the following printer options:

- Thermal printer - you can only print on the device. The optional thermal printer supports all printing formats, including resting ECG auto/rhythm printing, and stress ECG report printing.
- Laser printer - you can print locally on the device where a laser printer is attached or through the network to a remote laser printer. The laser printer supports all formats except for the continuous/real-time printing.
- Remote printers - if ST80i is set up to connect remotely to a default laser printer, this printer path needs to be setup first. The remote printers support all formats except for the continuous/real-time printing.

The default printer is configurable in the Settings section of the application. However, you can manually change the settings on the Report screen using the **Print (Quick Print Settings)** button.

You can print on either the thermal printer or a laser printer using standard paper. If you print to a laser printer, you can preconfigure the grid to print on standard paper. This setting option for each report is in the user profile (Settings → User Profile → ECG Report, Events Report,

Rhythm Report, Final Report).

Printed reports provide a calibration pulse on printed waveform reports for added check on print speed and amplitude accuracy.

In the Settings section of the application (Settings → System Settings → System), you can preconfigure the printer for each type of report:

- Select ECG Report Printer:
  - Off
  - Local Thermal Printer
- Select Event Report Printer:
  - Off
  - Local Thermal Printer
- Select Rhythm Report Printer:
  - Off
  - Local Thermal Printer
- Select Final Report Printer:
  - Off
  - Local Thermal Printer

WARNING ECG signals printed on a laser report should not be used to make time-sensitive or amplitude-sensitive measurements directly from printed page.

WARNING You are expected to provide power for the laser printer from a source other than the ST80i isolation transformer in order to be in compliance with your facility's safety requirements or IEC 60601-1.

WARNING The PC, LCD display, thermal printer, desk light, and NIBP/SpO2 module must be plugged into medical isolation transformer provided with the stress system.

Print Report Settings

During the exercise stress test, ST80i supports several kinds of printing including:

- Resting 12- Lead ECG report (with interpretation)
- Stage printout (without interpretation)
- Event printout (without interpretation)

- Real-time rhythm printing

ST80i produces an interpretive report. The interpretive components are printed at the top of an ECG record.

The interpretive report components consist of:

- Global ECG measurements: Heart Rate, PR Interval, QT Interval and QTc, Frontal Plane P, QRS and T axis.
- Interpretive statements (left-hand side)
- Reasons (right-hand side)
- Severity label

All the interpretation components are stored in the ECG file.

When printing a Final Stress Report, you can choose which individual reports to include and the number of copies to print for each individual report.

Print report settings are pre-configured in the user profile for the following reports:

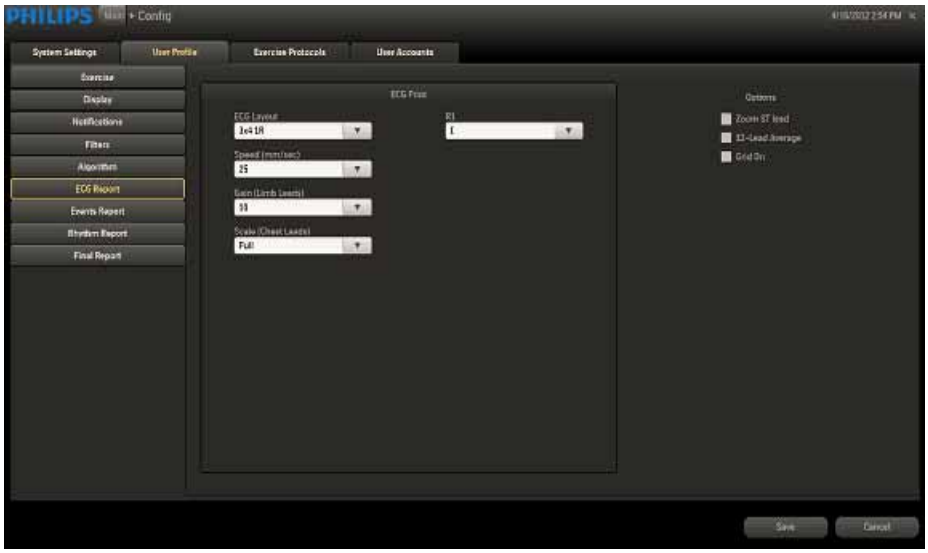
- ECG Report
- Events Report
- Rhythm Report
- Final Report

ECG Report

The print report settings for the ECG Report include:

- ECG Layout (select lead format)
- Speed
- Gain
- Scale
- R1
- Options (Zoom ST Map, 12-Lead Average, Grid On)

Figure 4-11 ECG Report Settings

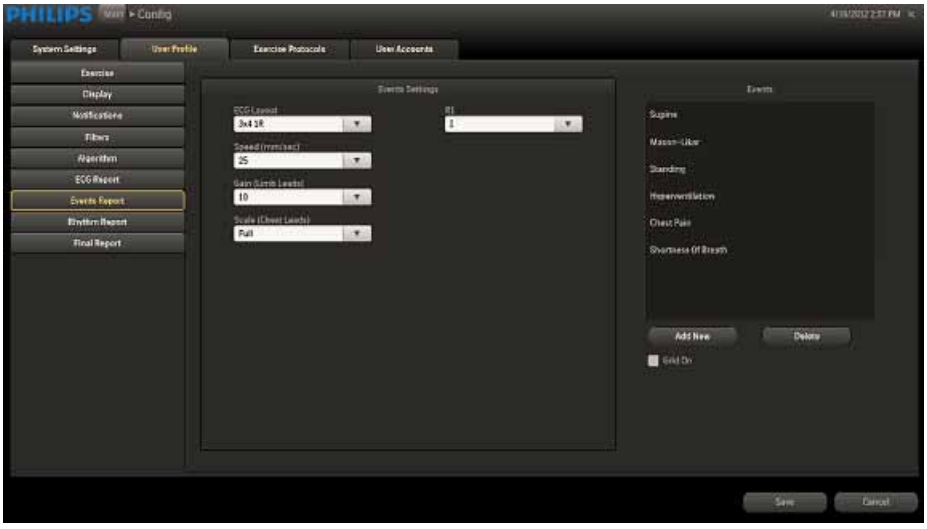


Events Report

The print report settings for the Events Report include:

- ECG Layout (select lead format)
- Speed
- Gain
- Scale
- R1
- Events
  - Supine
  - Mason-Likar
  - Standing
  - Hyperventilation
  - Chest Pain
  - Shortness of Breath
- Add New
- Delete
- Grid On

Figure 4-12 Events Report Settings



Rhythm Report

The print report settings for the Rhythm Report include:

- ECG Layout (select leads)
- Rhythm Settings
  - Speed
  - Gain
  - Scale

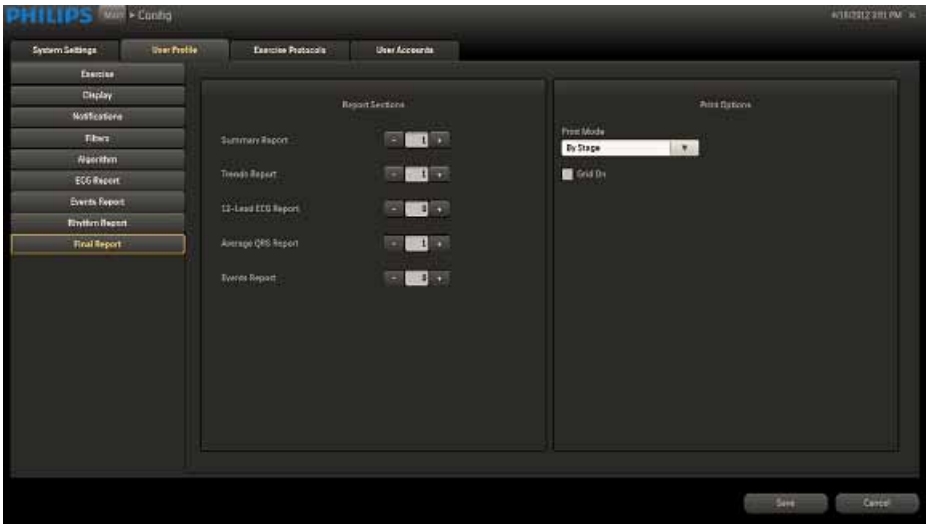
Figure 4-13 Rhythm Report Settings

Final Report

The print settings for the Final Report include:

- Summary Report (set number of copies)
- Trends Report (set number of copies)
- 12-Lead ECG Report (set number of copies)
- Average QRS Report (set number of copies)
- Events Report (set number of copies)
- Print Options
  - Print Mode (By Stage, By Minute)
  - Grid On

Figure 4-14 Final Report Settings



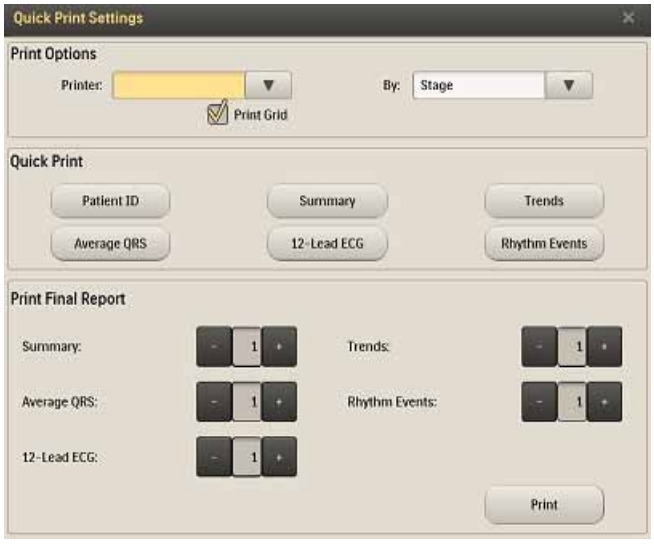
Print (Quick Print Settings) Button

On the Report screen, the **Print** button on the Procedure bar is used for printing both the Final Stress Report and individual reports. With the Quick Print Settings feature, you can override the following preconfigured settings:

- Final Report
  - Printer selection
  - Print mode (by stage, by minute)
  - Print Grid (on or off)
  - Number of copies to print
- Individual Reports
  - Printer selection
  - Print mode (by stage, by minute)
  - Print Grid (on or off)
  - Number of copies to print

When you click the **Print** button, the Quick Print Settings dialog box is displayed.

Figure 4-15 Quick Print Settings



- Print Options
  - Printer
  - By Stage, By Minute
  - Print Grid checkbox
- Quick Print
  - Patient ID

  - Average QRS
  - Summary
  - 12-Lead ECG
  - Trends
  - Rhythm Events
- Print Final Report
  - Summary [number of copies]
  - Average QRS [number of copies]
  - 12-Lead ECG [number of copies]
  - Trends [number of copies]
  - Rhythm Events [number of copies]
- **Print** button

NOTE Regardless of which option you choose, a Summary Report will always be printed on the first page of a final report.

You have the option to de-identify or hide a patient's name on individual to final reports before printing. See “De-Identify the Report” on page 4-35 for how to protect a patient's confidential information when printing individual and final patient reports.

Printing the Final Report

The Final Stress Report includes:

- Summary Report

NOTE The Summary Report cannot be printed without patient demographics.

- Trends Report
- 12-Lead ECG Report
- Average QRS Report
- Rhythm Events Report

When you log into ST80i, the active settings of the filters are from a stored default set associated with your log-in credentials. The same filter settings apply to both displayed and printed waveforms. The filter settings are printed with the report.

NOTE A Patient ID Report is printed at the beginning of each stress test and also in the Final Stress Report.

To de-identify the report, see See “De-Identification” on page 3-46.

To use the Print (Quick Print Settings) button to print the Final Stress Report

1. Select the printer from the drop-down list:
   - PDF Complete
   - Microsoft XPS Document Writer
   - Fax
   - Local Thermal Printer
2. Select the print parameters:
   - By Stage
   - By Minute
3. Place a checkmark in the “Print Grid” box, if you want the grid to print on laser paper.
4. Select the reports you want to include in the Final Stress Report.
5. Select the number of copies to print for each report, using the minus (-) and plus (+) indicators.
6. Click the **Print** button.

For more information on the configuration of printers, see “Printer Configuration” on page 4-25.

Printing Individual Reports

Both before and after you save the report, you can print individual reports using the **Print (Quick Print Settings)** button on the Report screen.

See “De-Identify the Report” on page 4-35.

To use the Print (Quick Print Settings) button to print individual reports

1. Select the printer from the drop-down list:
   - PDF Complete
   - Microsoft XPS Document Writer
   - Fax
   - Local Thermal Printer
2. Select the print parameters:
   - By Stage
   - By Minute

3 Place a checkmark in the “Print Grid” box, if you want the grid to print on laser paper.

4 Select which report (or reports) you would like to print from the Quick Print section:

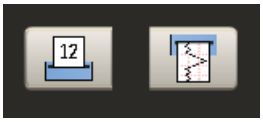
- Patient ID
- Average QRS
- Summary
- 12-Lead ECG (Full Disclosure)
- Trends
- Rhythm Events

Post-Recovery ECG Printing

The two print options at the bottom of the Report screen are used to print the current lead (or any lead you select) during Post-Recovery.

- Print 12-Lead ECG Report
- Start Rhythm Printing

Figure 4-16 Print Options



When you click the Print 12-Lead ECG Report, you will get a printout of that segment of the ECG.

When you click the Start Rhythm Printing button, a rhythm strip begins printing. To turn off Rhythm Printing, click this button again.

De-Identify the Report

You have the option to hide the patient's name when printing individual reports or the Final Stress Report. This feature allows you to hide patient identification information to protect the patient's identity. To de-identify the report, see “De-Identification” on page 3-46.

Working with Archived Reports

The Report database (also referred to as stress study database or stress study archive) is a long-term repository for on-line storage and access of stress study data. It may be located in either of the following:

- on a stress device for stand-alone stress device configuration, or
- on a central server, shared by one or more stress devices, in a “central system” configuration

All the stored stress tests can be loaded for full disclosure review. Once a test is loaded from the stress database, you can print the full data directly or print it after the final report from the Report screen.

For each stress study, a database is generated to archive patient demographics, reports, and full disclosure data. Together with the stress study data, patient information, the events captured during the testing, protocol settings and the algorithm output are also saved into this database.

The final report raw data and metadata is archived to the system database hosted locally on the device. he final report in PDF format can be exported to and stored on a central system.

Report (Stress Study) Database

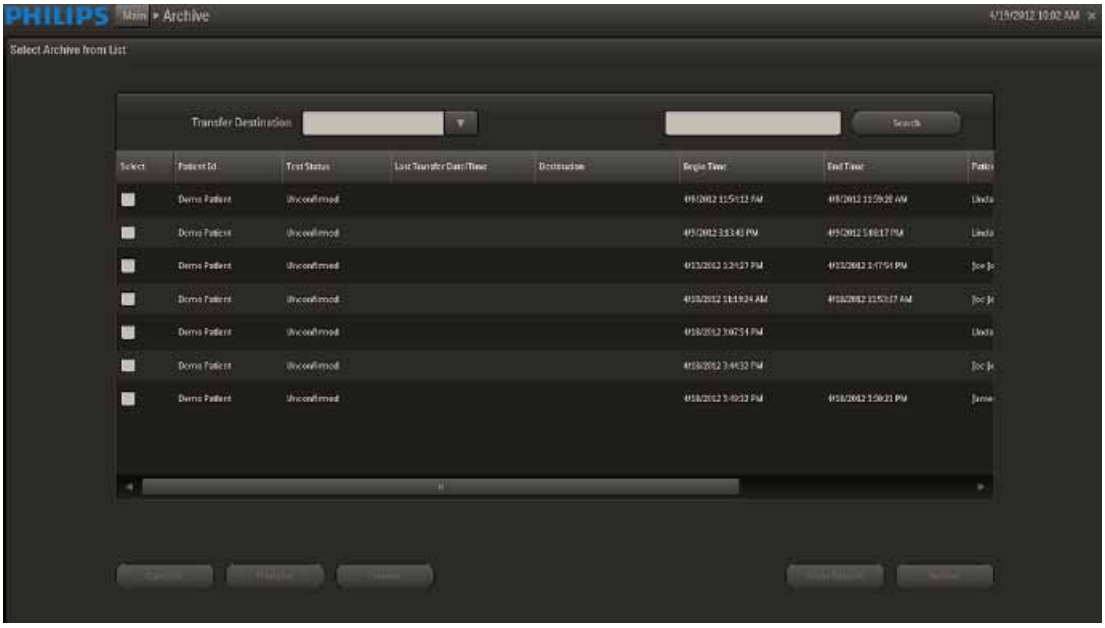
Access to the Report database is determined by role and permission level, which are associated with your log-in credentials. Functions that you are not authorized to perform are disabled on the screen. Only users with proper credentials are allowed access to the stored tests.

To display the Archive screen

▶ Click **Report** on the Main screen.

The Archive screen appears, listing all stored reports. A vertical scroll bar appears on the right side when the list is longer than the available space on the screen.

Figure 4-17 Select Archive From List Screen



Database Configuration

ST80i consists of two major components:

- Client side – provides the clinical interface to the patient and user interface to the technician. It handles the patient's data acquisition, stress procedure workflow, data analysis, stress report presentation and raw data storage.
- Server side – provides data storage and retrieval for the stress final reports in PDF format. The server side also provides support for workflow, audit/tracking, and user authentication / authorization (deferred).

The Client and Server components may be co-located on the same physical PC, or may be installed on separate PC platforms.

In each mode, the data store limit is determined by the storage capacity of the hard disk.

See the *ST80i Installation and Configuration Guide* regarding database storage on networked devices.

Depending on your facility's network configuration, ST80i can either work as a single, stand-alone device or as a set of multiple, connected devices. As a stand-alone device, ST80i provides basic server functions to perform a stress test, such as user security, configuration management, and ECG data storage.

NOTE All reports (including unconfirmed/non-finalized reports) should be maintained in the Archive.

STAND-ALONE DEVICE

If you are using a stand-alone device with built-in stress study database deployment, all exercise stress test reports will be permanently stored in the device database archive.

Using a stand-alone device, you can review, edit, save and sign the stress report from the Report screen.

The locally stored stress test is viewable and printable from the Report screen.

CENTRAL SERVER

In addition to local storage, you can configure archived stress tests in multiple networked locations.

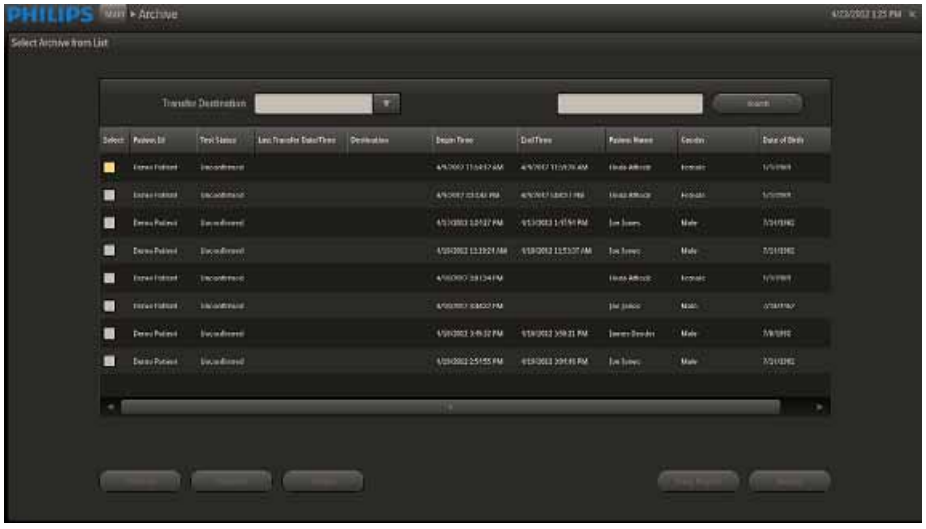
When several ST80i devices are connected, a backend system server is used to provide the data storage service. In this mode, each ST80i device must maintain the raw data of the stress studies and the final stress study report in PDF format that can be transferred to the central database when network connection is available.

The stress test on the central server is stored in PDF format that is viewable on the client side. The PDF filename is a 128-bit GUID.

Patient Reports

The Archive screen provides a list of archived stress tests that are stored locally or on the server.

Figure 4-18 Select Archive from List Screen



The Select Archive from List screen includes the following information:

- Patient ID
- Test Status

- Last Transfer Date/Time
- Destination
- Begin Time
- End Time
- Patient Name
- Gender
- Date of Birth

The test status is listed as follows:

- Confirmed
- Unconfirmed
- Exported

From the Select Archive from List screen, you can:

- Search for reports
- Confirm reports
- Transfer reports
- Delete one or more stored reports (administrative users only)
- Backup reports to another location (administrative users only)
- Restore reports from another location (administrative users only)
- View reports
- Replay reports

NOTE A stress study report cannot be confirmed or exported to TMVue if its required patient fields are not complete.

Search for Reports

The Archive screen allows you to search for reports to confirm, transfer, delete, backup, restore, view, or replay. You may search for reports by using the Search textbox and button or by using the column headings to sort the reports.

To search for reports using the Search textbox and button

1 Type the search criteria into the textbox to the left of the **Search** button. You may use Patient ID, Patient Last Name, or Patient First Name as search criteria.

Figure 4-19 Search Textbox and Button

2 Click **Search**.

The Select Archive from List screen displays only the results that match the search criteria.

To search for reports using column headings to sort the reports

- Click a column heading (e.g., “Patient ID,” “Patient Name”) to sort archived patient reports.

  The Archive screen sorts the contents of that column in ascending or descending order.

  Click the column heading again to reverse the sorting order

Confirm a Report

To confirm a patient report -- *procedure in development--*

1 Select the patient by putting a checkmark in the box by the patient ID.

2 Click the **Confirm** button.

3

4

A stress study report cannot be confirmed or exported to TraceMasterVue if the required patient fields are not complete.

Transfer Reports

To transfer a patient report -- *procedure in development--*

You can select single or multiple reports to export to a remote server. When exporting multiple reports, you can cancel the exporting command. Any error during the operation should be clearly prompt and will not block the whole operation.

1 Select the patient report(s) to transfer by putting a checkmark in the box(es) in the Select column to the left of the Patient ID.

NOTE To select all of the reports, click the Select column heading; to deselect all of the reports, click the Select column heading again.

2 Select the destination for the transfer from the Transfer Destination drop-down list.

Figure 4-20 Transfer Destination Drop-Down List

3 Click the **Transfer** button.

Delete Reports

If you have administrative privileges, you can select single or multiple stress studies to delete. When doing this, you will be warned about the potential data lost. When deleting multiple studies, you can also cancel the operation to stop the delete process.

To delete reports

1 Select the patient report(s) to delete by putting a checkmark in the box(es) in the Select column to the left of the Patient ID.

2 Click the **Delete** button.

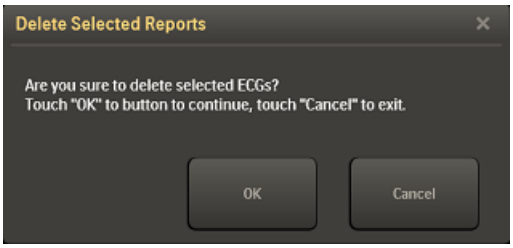
The Confirm Report window is displayed

Figure 4-21 Confirm Report Window

3 Type your User ID and password, and click **OK**.

The Delete Selected Reports window is displayed.

Figure 4-22 Delete Selected Report Window



WARNING This procedure will permanently delete the reports (raw data and metadata) from the local database or the PDF reports from the central server.

4 Click **OK** to delete the report(s); click **Cancel** to exit.

Backup Reports

If you have administrative privileges, you can select single or multiple stress studies to backup to another location.

To backup reports -- *procedure in development--*

1

2

3

4

5

Restore Reports

If you have administrative privileges, you can select single or multiple stress studies to restore from another location.

To restore reports -- *procedure in development--*

1

2

3

4

5

View a Report

To view a saved patient report

1. Select the patient report by putting a checkmark in the box by the patient ID.
2. Select the **View Report** button.

   The Report screen opens.

NOTE Double-clicking on the study record also brings up the report

Replay a Report

To replay the patient ECG from the Archive screen

1. Select the patient report by putting a checkmark in the box by the patient ID.
2. Click the **Replay** button.

   The Patient Session is loaded, beginning with Exercise.

This option provides you with the ability to scan the entire ECG from start to end.

When reviewing the stored stress test, you can change the J+ms value and change the reference ECG. The stress study data and configuration settings are saved in database.

Viewing Reports Saved as PDF Files

To view a PDF file

1. Exit the ST80i application.
2. From Windows Explorer, locate and select the directory where the file was exported.
3. Locate the file you want to review and double-click it.

   Adobe Acrobat Reader automatically opens and displays the file.
4. Press **Page Down** and **Page Up** to navigate through the file.

If ST80i is connected to a printer, you can print the file by selecting File, then Print.

Exporting Reports (Export Exam)

When a final stress report is saved, it may then be exported to the central server. The report can be finalized and signed on both device side and server side. The stress study raw data will be saved in local stress study database. The export status and date/time of last export are also maintained.

The final stress report may also be exported into a PDF file format. The PDF format can be used on any PC for review and then emailed to the referring physician. It is also possible to export a report directly to external media such as a USB flash stick in PDF format.

NOTE To export a report, you need the appropriate permission level.

Additionally, you can export PDF files for import into the Philips IntelliSpace Enterprise ECG Manager (version C.04 and later) or the Philips TraceMasterVue ECG Management System (version C.01 through C.03) for storage and archiving. See “Exporting Reports to an ECG Management System” on page 4-46 for more information.

You can still print the report from ST80i at any time. You can also print the PDF file through Adobe Acrobat. The exported report follows all the settings for the final stress report. See “Printing the Final Report” on page 4-33.

On the Report screen, you can select ECGs from a storage location and copy/export them to a remote system using the Copy/Transmit function. The format of the exported study record is PDF.

ST80i’s Trinity Support allows for export of ECG data in ST80i format for inclusion in a combined Stress/Echo image report. The folders used for raw data sharing with Trinity for Q-Station, need to be locked down by appropriate folder permissions on the shared drive.

See the *ST80i Installation and Configuration Guide* for how to create folder permissions to protect data.

To export a final stress report

1. Click the **Confirm** button.
2. Fill in your User Name and Password
3. Click **OK**.

NOTE A stress study report cannot be confirmed or exported to TMVue if its required patient fields are not complete.

External Storage of Stress Study data

If you have administrator access, you can copy stress study data from the Report database and move the information to an external storage location (such as removable hard disk and USB stick).

ST80i provides an indication that the stress data has been copied to an external location. Once the Stress study data has been copied/moved to an external location, it may be deleted if desired. If deleted, a pointer will remain in the stress study database indicating that the data had been moved to external storage.

An alert indicates the exporting status, i.e. success or failure. If failure, the error code should be also provided.

In addition to local storage, you can configure archived stress tests in multiple networked locations. On a stand-alone single device with built-in stress study database deployment, all stress test reports are permanently stored in the device database archive.

ECG Export Destination Sites

You may select the destination site from a list of preconfigured sites. Each preconfigured site includes the following information:

- Site label (user-defined)
- If the site is on a network, address and other connection details (URL, node number, etc.)
- The following remote system types are supported:
  - TraceMasterVue
  - ECG Gateway

Once the connection is established, all selected ECGs are transferred to the remote site. After each ECG has been successfully transmitted, the information is logged.

If the connection fails, the operator is given an alert. No attempt is made to automatically retry the operation.

A maximum of 100 Remote Sites profiles can be created without noticeable performance degradation when switching screens.

To create remote sites, see the *ST80i Installation and Configuration Guide*.

Exporting Reports to an ECG Management System

You can export PDF files for import into the Philips IntelliSpace Enterprise ECG Manager (version C.04 and later) or the Philips TraceMasterVue ECG Management System (version C.01 through C.03). You can review the ECG, as well as store it in the database. You cannot, however, edit the imported PDF file. For details about working with the imported PDF report, refer to the ECG management system documentation.

If you are exporting to an ECG manager, shared folders with the appropriate permissions must be set up on the server. You can specify a separate profile for each type of exported file and also to export to different directories. Check with your system administrator to see which profile you should use to export to the IntelliSpace or TraceMasterVue systems.

File Naming Conventions

ST80i saves files in a particular naming convention. It is very important that you do not change this convention and that you enter all required information in the Patient Information screen. Files that are not named properly will get sent to the TraceMasterVue Error directory.

CAUTION The underscore, square brackets, and lack of spaces are always present in the file name and are not removable. They are required for proper parsing of the PDF files during import into the TraceMasterVue database. Stress files must conform to the naming conventions specified here to be able to be imported into the TraceMasterVue database.

ST80i file names are of the form: ***--- procedure in development--***

SV_PatientID[Date+Time]FirstName_MiddleInitial_LastName.pdf

where

SV - required AppName format

PatientID - required

Patient identification number or MRN (if provided)

[Date+Time] - required

The date and time shown is the date and time that the study was acquired.

- Date format: YYYYMMDD
- Time format: HHMM

FirstName - optional

Patient first name

MiddleInitial - optional

Patient middle initial

LastName- optional

Patient last name

To export a report for TraceMasterVue

1. Save the final report as described in “Saving the Final Stress Report” on page 4-23.
2. Click **Export** to save it as a file.

If the file is named correctly, it will be exported to the directory specified in the Miscellaneous tab of the User Profile Configuration window for import into TraceMasterVue.

3. To automatically remove the report from ST80i after export, check Delete exam after export.

IMPORTANT! You cannot recover deleted exams! Use this option, if at all, with great caution.

ST80i prompts you to confirm this selection.

ST80i places a Y next to this report in the Exp column on the Archive screen.

Importing Reports

You can download pdfs from a TraceMasterVue remote site or import data from a Synapse remote site.

Download Pdfs from a TraceMasterVue Remote Site

To download pdfs from a TraceMasterVue Remote Site ***-- procedure in development--***

1 On the Worklist tab of the Select Patient screen, select “TraceMaster” from the Location drop-down list.

Figure 4-23 Location Drop-Down List

2 From the Worklist, place a checkmark by the name of the patient for whom you want to view a previous ECG.

3 Click the **Previous ECG** button.

A list of the patient’s previous ECGs is displayed.

4 .....Need steps to open the pdf....

Import Data From a Synapse Remote Site

How to import data from a Synapse Remote Site -- *procedure in development--*

1 On the Worklist tab of the Select Patient screen, select “Synapse” from the Location drop-down list.

Figure 4-24 Location Drop-Down List

2 Click the Download button.

The worklist is downloaded to the table.

3 .....Next steps???

5

Maintaining the ST80i System

This chapter describes routine maintenance and cleaning of your ST80i system. It provides the following information:

Precautions

- Before cleaning any equipment, unplug the AC power cord connecting the equipment to the power source.
- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning.
- Wipe the exterior surface of the device and patient cables with a non-alcohol sterilizing disinfectant, and then dry with a clean cloth.
- Conductive parts of the patient cable, electrodes, and associated Type CF connections, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after use by forming them into a loose loop.
- Proper patient preparation is important for proper application of ECG electrodes and operation of the device.
- Patient cable exteriors should be checked for cracks or breakage prior to use.

Are these correct???

- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Class I equipment
  - Type CF applied parts

- Ordinary equipment
- Not suitable for use in the presence of flammable anesthetics
- Continuous operation

CAUTION Dispose of waste material according to local regulations and laws regarding medical and battery waste.

Cleaning the ST80i System

To clean the system, including PC, monitor, and transport cart

- Clean the mouse every month, as follows:
  - **a** Remove the ball from the mouse base.
  - **b** Wipe the ball with a dry cloth.
  - **c** Reassemble the mouse.
- Clean the keyboard with a damp cloth, as necessary.
- Clean the outside of the computer with a soft cloth lightly moistened with a mild detergent solution. Do not use solvents or abrasive cleaners.
- Clean the display with a soft cloth lightly moistened with a mild detergent approved for use on the display. Do not use solvents or abrasive cleaners.
- Clean the cart with a damp cloth, as necessary.

ST80i components should withstand cleaning using a cloth dampened with the following solutions.

IMPORTANT! This applies only to "Philips Healthcare custom-designed components". For all COTS components, including laser printers, LCD displays, keyboards, and mice, customers must follow the manufacturers' cleaning specifications.

- Isopropyl alcohol, 70% solution
- Mild soap and water
- Chlorine bleach (5.25% sodium hypochlorite content), 3% solution in water
- Steris Coverage Plus NPD, 1/2 fluid ounce per gallon water (one part Coverage Plus NPD to 256 parts water)

Labels and graphics are to remain intact and legible. There is to be no damage, discoloration, stress cracking or crazing of parts, cracking or elastomeric swelling. Parts shall not be attacked to the degree that they lose their gloss or become sticky or gummy.

Maintaining the ST80i Thermal Printer

You should implement a satisfactory cleaning and inspection schedule for this equipment for proper equipment operation and to reduce the possibility of equipment failure.

NOTE There are no serviceable parts for this printer. Should you experience problems with the printer, it is replaced as a whole.

Inspecting the ST80i Thermal Printer

Inspect the equipment for the following conditions on a regular basis:

- Examine power cable and the network cable for obvious damage (for example, torn insulation, broken connectors, and so on). Replace cables as necessary.
- All cords and connectors are securely seated in their corresponding connections.
- Examine the equipment for missing screws, cracks or broken areas that might allow unintended access to internal electronics areas

Cleaning the ST80i Thermal Printer

NOTE If the system is configured with a laser printer, refer to the User Guide provided with the printer for maintenance and cleaning instructions.

To clean the printer

1. Disconnect the power source.
2. Clean the exterior surface of the unit with a damp cloth using a solution of mild dishwashing detergent diluted in water.
3. After washing, thoroughly dry off the unit with a clean, soft cloth or paper towel.

Clean the print head monthly, as described next.

To clean the print head

NOTE Do not let soap or water come into contact with the writer, plugs, jacks or vents.

1. Open the writer door.
2. Lightly rub the print head with an alcohol pad.
3. Wipe with a clean cloth to remove alcohol residue.
4. Allow the print head to air dry.
5. Clean the platen by using adhesive tape. Apply the tape and pull it off. Rotate roller and repeat until entire roller is clean.
6. Clean the paper sensor.

Testing Printer Operation

After inspecting and cleaning the thermal printer, confirm that the printer is working properly.

To test printer operation

- Using an ECG simulator with the stress testing system, acquire and print ECGs of known amplitude.

A successfully printed ECG report has the following characteristics:

- Printing should be dark and even across the page.
- There should be no evidence of print-head dot failure (for example, breaks in printing forming horizontal streaks).
- Paper motion should be smooth and consistent during printing.
- Waveforms should appear normal, with proper amplitude, and without distortion or excessive noise.
- Paper should stop with perforations near the tear-bar (indicating proper cue sensor operation).

Replacing the ST80i Thermal Printer Fuse

The AC fuse needs to be replaced when the AC power on indicator light does not illuminate when the printer is plugged into AC power.

Figure 5-1 AC power on indicator light on ST80i thermal printer

A AC power on indicator light

Only use replacement AC fuses with Philips part number 453564131221, or use a 1.6 amp (250V) time-delay fuse the same size and configuration as the original fuse.

Figure 5-2 Replacing the AC Fuse

A AC Fuse

To replace the AC fuse

1. Unplug the thermal printer from AC power. Pull out the AC power cord from the AC power connector on the rear of the printer.
2. Locate the AC fuse, which is directly below the AC power connector.
3. Push on both ends of the fuse and pull out the fuse from the fuse holder slot.
4. Insert the new fuse using the same orientation.
5. Push the fuse all the way into the fuse holder slot. The fuse snaps into place.

Cleaning the Equipment

The wireless patient module (PIM), PIM holder, and lead wires must be cleaned after each use.

To clean the PIM, PIM holder, USB interface, and lead wires

1 Dampen a soft cloth with one of the disinfectants or cleaning agents listed below. Clean the lead wires with any of the following:

- Cidex Ortho Phthaladehyde
- Cetylcide
- Vesphene 2 Aqueous Phenolic Germicidal Agent

CAUTION **Do not:**

- Use isopropyl alcohol
- Autoclave the patient module, patient cable/lead wires, or use ultrasonic cleaners
- Immerse
- Use abrasive materials
- Wet the connectors

2 Wring excess moisture from the cloth before cleaning.

3 Simply wipe off the exterior of the PIM, PIM holder, and the USB interface connector.

A

Troubleshooting and Contacting the Response Center

When you encounter a problem working with ST80i, address the issue in the following order:

1. Review the Troubleshooting chapter to see if your issue is addressed.
2. Contact your ST80i administrator.
3. Contact the Philips Healthcare Customer Care Solution Center.

The Philips Response Center can assist with product troubleshooting and provide technical expertise to help with any issue with the ST80i system. For details, visit the following URL on the Web:

www.medical.philips.com/main/services/response_center

This appendix provides the following information:

Troubleshooting ST80i Issues

When you are using ST80i, you may encounter some problems with the system. The following table describes some of the more common symptoms and provides information regarding possible causes, and solutions to help you solve potential problems.

Table A-1 Troubleshooting ST80i issues

Problem	Cause	Solution
Waveform Issues		
Baseline drift	Poor skin-to-electrode contact.	Re-prep skin and replace faulty electrodes.
A red dashed line displayed on the real-time ECG display	■ Lead failure caused by inadequate skin-to-electrode contact. ■ Broken lead wire. ■ RF interference (wireless option only). ■ Faulty PIM/USB module	■ Correct the faulty lead identified on the lead map dialog. ■ Replace the lead wire. ■ If problem persists, contact the Response Center. ■ ■ Perform an RF scan to determine the presence of RF interference. Select the optimal channel. Ensure the channel specified in the ST80i application and on the wireless patient module is the same. ■ Reseat USB cable. ■ Ensure correct USB type is selected in System Settings.
ECG artifact caused by muscle interference.	Electrode placed over an area of muscle or fatty tissue.	Find a stable electrode site, re-prep the skin, and apply a new electrode away from muscular and fatty areas.

Table A-1 Troubleshooting ST80i issues

Problem	Cause	Solution
System Navigation Issues		
No response to keyboard commands.	■ USB cable connection.	■ Check USB cable connection. ■ Disconnect and connect the keyboard to check whether keyboard can be identified by the system
Cursor does not move	■ USB cable connection.	■ Check USB cable connection. ■ Disconnect and connect the mouse to check whether mouse can be identified by the system.
Treadmill Issues		
Treadmill does not respond to the On command from ST80i	■ Equipment was powered up in the wrong sequence.	■ Turn the treadmill off by using the **Stop Treadmill** button. Wait one minute and turn the power On. Proceed with the test. ■ Ensure the correct equipment is specified in the Configuration settings.
	■ The Treadmill power switch is in the Off position, or the treadmill cable is not properly attached.	■ Check the treadmill-to-ST80i cable connection. Turn the Treadmill main power switch to the On position. The switch is located at the base of the treadmill hood, on the left side.
		■ Ensure the correct COM port is configured.
	■ The **Emergency Stop** button is engaged.	■ Reset the **Emergency Stop** button by turning it clockwise one quarter turn.
System Error Messages		
Error message appears: No exams are currently selected	An attempt to access a final report is made, but no patient is selected from the list.	Click on the patient name to select it, then access the file.

Table A-1 Troubleshooting ST80i issues

Problem	Cause	Solution
System Error Messages *(continued)*		
Error message appears: Not all of the selected exams are reported	■ An attempt was made to print or export a final report from the Archive Manager but the report has not been saved as Reported.	■ A test is labeled Reported only after it is saved. Click **Save Report**, then export the final report.
Error message appears: Not reported exam	■ An attempt to print a final report from the Report screen is made but the report has not been saved as Reported.	■ A test is labeled Reported only after it is saved. Click **Save Report**, then export the final report.
The Lead Map display a red “X” on one or more connections	One or more leads have failed.	Connect the electrodes. Once connected, the warning message disappears.
An error occurred during export of selected exams	One or more leads have failed.	■ Check Export directory. ■ Check remote location. ■ Try pinging remote location.
Error message appears: No stage selected	In the protocol edit function, an attempt is made to edit a stage, but no stage has been selected.	Double-click on the stage to edit. The Edit window appears, allowing you to change the stage parameters.

Table A-1 Troubleshooting ST80i issues

Problem	Cause	Solution
Printer Issues		
■ Thermal printer paper out light is on ■ Thermal printer is not printing	■ Paper jammed. ■ No paper in tray. ■ Open writer door.	■ Open writer cover and remove jammed paper. ■ Insert new pack of paper in tray. ■ See if writer door is latched. ■ Verify that the correct printer is specified in the configuration settings. See “Printer Configuration” on page 3-42.
■ Uneven printing of ECGs or reports	■ Printer head needs cleaning. ■ Paper door not closed completely.	■ Refer to cleaning instructions in Chapter 5, “Maintaining the ST80i System.” ■ See if paper door is closed completely.
Uneven printing	Possible causes of uneven printing: ■ Print head itself ■ Platen ■ Poor or damaged paper ■ Mechanical misalignment of the print head	Have a technician: ■ Check the platen for uneven wear. ■ Verify that the print head shoulder screws are secure before replacing the print head. The shoulder screws that secure the print head should be properly centered in their holes, allowing the print head slight vertical movement.
Gaps in printing	■ Print head and signal cables may have a short or damaged connectors ■ Defective print head ■ Faulty circuit board ■ Defective paper ■ Dirty print head	Have a technician: ■ Check the print head and signal cables for shorts, opens, or damaged connectors. These cables plug in between the circuit board and the thermal print head. ■ Check the print head and circuit board and replace as needed. ■ Replace the paper, using a fresh pack of properly stored paper. ■ Clean the print head.

Table A-1 Troubleshooting ST80i issues

Problem	Cause	Solution
Printer Issues *(continued)*		
No printing	■ LAN settings may be incorrect. ■ Network cable may be loose. ■ Power cord may be disconnected. ■ Printer might not have paper loaded. ■ Printer error.	■ Check to see that the Local Area Network Connection Properties settings on the PC are defined correctly ■ Ensure that a crossover network cable is used and check connections. ■ Make sure both printer LAN LEDs (Amber and green) are lit ■ Ensure the printer port is enabled. ■ Check AC power cord connections and confirm that the Power On indicator is illuminated. ■ Check to see that paper has been loaded and that it has been loaded correctly. Paper sensor mark is at the bottom right.
No motor drive	■ Insufficient paper tension ■ Faulty writer assembly ■ Faulty circuit board	Check and replace as needed.
Defective paper	Thermal paper that is old or that was improperly stored can cause light or uneven printing. Exposure to heat or chemical vapors can damage the paper.	Test printer using a fresh pack of properly stored paper.
Blood pressure printout and report discrepancy	Use of NIBP field to enter new blood pressure values.	You must enter blood pressure values using the BP mmhg field in the Side Panel. For details on entering blood pressure values, see “NIBP & SpO2” on page 3-29.

Table A-1 Troubleshooting ST80i issues

Problem	Cause	Solution
Data-Entry Issues		
Cannot manually enter patient data	It is possible that the Export HL7 check box has been inadvertently selected on the Miscellaneous tab in the Configuration settings.	For the affected profile(s), do the following: **1** Click **Settings**, then click the Miscellaneous tab. **2** Ensure the Export: HL7 check box is clear. **3** Click **Save Profile** and **Exit**.
Wireless Patient Module Issues		
Packet errors/ signal drop	Signal on the screen shows a red dashed line.	Configure the system to automatically hop the RF channel, or perform an RF Scan to locate the source of the interference and to change to the optimal channel for the wireless patient module. For details about the wireless settings, see the *ST80i Wireless Patient Module Instructions for Use*.
Wireless Patient Module Issues *(continued)*		
No waveform signal on the screen	With the patient (or simulator) connected, no waveforms are displayed; only the red dashed line and lead-fail indicator appear. **NOTE** If neither the signal nor the red dashed line is present, click the "X" in the upper right corner of the screen, and then click **OK** in the "Abort Test" dialog box.	Check the ST80i System settings, as well as the wireless patient module to ensure that the two units are set to the same channel. For details about setting the receiving channel settings, see the *ST80i Installation and Configuration Guide*. For details about the wireless settings, see the *ST80i Wireless Patient Module Instructions for Use* for instructions.

Contacting Technical Support

Philips Healthcare Customer Care Solution Center

North America

Country	Telephone Number
Canada	(800) 323 2280
United States Miami (Spanish speaking)	(800) 722-9377, press option 3 954 835 2650

South America

Country	Telephone Number
Argentina	54 11 4546 7698
Brazil	0800 701 7789
Chile	0800 22 3003
Mexico	01 800 710 8128
Columbia	01 8000 11 10 10
Peru	51 1620 6440
Puerto Rico	787 754 6811

Europe

Country	Telephone Number
United Kingdom	07 002 432 58 472 or 07 002 HEALTHRC
Austria	01 25125 333
Belgium	32 2 525 7102 (French) 32 2 525 7103 (Flemish)
Finland	010 855 2455
France	0803 35 34 33

Europe

Country	Telephone Number
Germany	0180 5 47 5000
Italy	0800 8256087
Netherlands	31 4 027 87630
Spain	34 90 230 4050
Sweden	08 5064 8830
Switzerland	0800 80 10 23

Asia Pacific

Country	Telephone Number
Australia	1800 251 400
China	800 810 0038
Hong Kong	852 2876 7578
India	
New Delhi	011 2695 9734
Mumbai	022 5691 2643/2431
Calcutta	2485 3718
Chennai	044 555 01000
Bangalore	080 5091 911
Hyderabad	040 5578 7974
Indonesia	021 794 7542
Japan	0120 381 557
Korea	080 372 7777 (toll free)
Seoul	02 3445 9010
Macau	0800 923
Malaysia	1800 886 188
New Zealand	0800 251 400
Philippines	02 845 7875

Asia Pacific

Country	Telephone Number
Singapore	1 800 Philips
Taiwan	0800 005 616
Thailand	02 614 3569

B

Protocol Reference

This appendix provides an example of each of the included protocols. You can define and edit protocols. For details, see *ST80i Installation and Configuration Guide*.

The following protocols are delivered with every ST80i system:

- Bruce (page B-2)
- Modified Bruce (page B-3)
- Balke (page B-4)
- Ellestad (page B-5)
- Naughton (page B-6)
- Pharmacological (page B-7)
- Low Ramp (page B-8)
- Medium Ramp (page B-9)
- High Ramp (page B-10)
- USAF/SAM 2.0 (page B-11)
- USAF/SAM 3.3 (page B-11)
- Cycle (Ergometer) (page B-12)
- Astrand (page B-13)

The following sections provide an example of each of these protocols.

Bruce Protocol

This sample Bruce protocol produces the following operations and conditions:

- A stage change occurs every 3 minutes with an increase in treadmill speed and grade.
- Blood pressure is automatically measured at the end of each stage.
- A 12-lead ECG report is automatically printed at the end of each stage. ECG acquisition begins 10 seconds prior to the end of a stage.
- In the Recovery phase, the treadmill slows to 1.5 mph and the following reports are automatically printed:
  - The Peak Exercise ECG report prints immediately.
  - A Recovery ECG prints in one minute.
  - A Recovery ECG prints every two minutes until the end of the Recovery phase.
- Blood pressure measurement is set to every 2 minutes (2, 4, 6, 8…) until the end of the Recovery phase.

Table B-2 Bruce Protocol Settings

Bruce						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	3.00	1.7	10.0	End	End
	2	3.00	2.5	12.0	End	End
	3	3.00	3.4	14.0	End	End
	4	3.00	4.2	16.0	End	End
	5	3.00	5.0	18.0	End	End
	6	3.00	5.5	20.0	End	End
	7	3.00	6.0	22.0	End	End
Recovery						
	1	3.00	1.5	0.0	Every 02:00	Every 02:00

Modified Bruce

Table B-3 Modified Bruce Protocol Settings

Modified Bruce						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	0.5	0.0	Off	Off
Exercise						
	1	3.00	1.7	0.0	End	Begin
	2	3.00	1.7	5.0	End	Begin
	3	3.00	1.7	10.0	End	Begin
	4	3.00	2.5	12.0	End	Begin
	5	3.00	3.4	14.0	End	Begin
	6	3.00	4.2	16.0	End	Begin
	7	3.00	5.0	18.0	End	Begin
	8	3.00	5.5	20.0	End	Begin
	9	3.00	6.0	22.0	End	Begin
Recovery						
	1	3.00	1.0	0.0	Every 02:00	Every 02:00

Balke Protocol

The Pre-Exercise and Recovery phase settings are the same as for the Bruce protocol. See Figure X-1, above.

Table B-4 Balke Protocol Settings

Balke						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	1.0	3.3	1.0	End	Off
	2	1.0	3.3	2.0	End	Off
	3	1.0	3.3	3.0	End	End
	4	1.0	3.3	4.0	End	Off
	5	1.0	3.3	5.0	End	Off
	6	1.0	3.3	6.0	End	End
	7	1.0	3.3	7.0	End	Off
	8	1.0	3.3	8.0	End	Off
	9	1.0	3.3	9.0	End	End
	10	1.0	3.3	10.0	End	Off
	11	1.0	3.3	11.0	End	Off
	12	1.0	3.3	12.0	End	End
	13	1.0	3.3	13.0	End	Off
	14	1.0	3.3	14.0	End	Off
	15	1.0	3.3	15.0	End	End
	16	1.0	3.3	16.0	End	Off
	17	1.0	3.3	18.0	End	Off
	18	1.0	3.3	20.0	End	End
	19	1.0	3.3	21.0	End	Off
	20	1.0	3.3	22.0	End	Off
	21	1.0	3.3	23.0	End	End
	22	1.0	3.3	24.0	End	Off
Recovery						
	1	3:00	1.0	0.0	Every 02:00	Every 02:00

Ellestad Protocol

The Pre-Exercise and Recovery phase settings are the same as for the Bruce protocol. See Figure X-1, above.

Table B-5 Ellestad Protocol Settings

Ellestad						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	3.00	1.7	10.0	End	End
	2	2.00	3.0	10.0	End	End
	3	2.00	4.0	10.0	End	End
	4	3.00	5.0	10.0	End	End
	5	2.00	6.0	15.0	End	End
	6	2.00	7.0	15.0	End	End
	7	2.00	8.0	15.0	End	End
Recovery						
	1	3.00	1.5	0.0	Every 02:00	Every 02:00

Naughton Protocol

The Pre-Exercise and Recovery phase settings are the same as for the Bruce protocol. See Figure X-1, above.

Table B-6 Naughton Protocol Settings

Naughton						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	0.5	0.0	Off	Off
Exercise						
	1	2.00	1.0	0.0	End	Off
	2	2.00	2.0	2.0	End	End
	3	2.00	2.0	3.5	End	Off
	4	2.00	2.0	7.0	End	End
	5	2.00	2.0	10.5	End	Off
	6	2.00	2.0	14.0	End	End
	7	2.00	2.0	17.5	End	Off
Recovery						
	1	3.00	1.0	0.0	Every 02:00	Every 02:00

Pharmacological Protocol

Table B-7 Pharmacological Protocol Settings

Pharmacological							
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*	*Dose*
Pre-Infusion							
	1	Unlimited	0.0	0.0	Off	Off	Off
Infusion							
	1	3.00	0.0	0.0	End	End	Off
	2	3.00	0.0	0.0	End	End	Off
	3	3.00	0.0	0.0	End	End	Off
	4	3.00	0.0	0.0	End	End	Off
	5	3.00	0.0	0.0	End	End	Off
	6	3.00	0.0	0.0	End	End	Off
	7	3.00	0.0	0.0	End	End	Off
Post-Infusion							
	1	3.00	0.0	0.0	Every 01:00	Every 02:00	Off

Low Ramp Protocol

The Pre-Exercise and Recovery phase settings are the same as for the Bruce protocol. See Figure X-1, above.

Table B-8 Low Ramp Protocol Settings

Low Ramp	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Pre-Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	0:30	1.0	0.0	End	End
	2	0:30	1.1	1.0	End	End
	3	0:30	1.2	1.0	End	End
	4	0:30	1.3	2.0	End	End
	5	1:00	1.4	3.0	End	End
	6	0:30	1.5	4.0	End	End
	7	0:30	1.6	4.0	End	End
	8	0:30	1.7	5.0	End	End
	9	0:30	1.8	6.0	End	End
	10	1:00	1.9	7.0	End	End
	11	0:30	2.0	8.0	End	End
	12	0:30	2.1	8.5	End	End
	13	0:30	2.2	9.0	End	End
	14	0:30	2.3	9.5	End	End
	15	1:00	2.4	10.0	End	End
	16	0:30	2.5	10.5	End	End
	17	0:30	2.6	11.0	End	End
	18	1.00	2.7	12.0	End	End
	19	0:30	2.8	13.0	End	End
	20	0:30	2.9	14.0	End	End
	21	1.00	3.0	15.0	End	End
	22	0:30	3.1	16.0	End	End
	23	0:30	3.2	17.0	End	End
	24	1.00	3.4	18.0	End	End
	25	1:00	3.6	19.0	End	End
Recovery						
	1	3:00	1.5	0.0	Every 02:00	Every 02:00

Medium Ramp Protocol

The Pre-Exercise phase settings are the same as for the Bruce protocol. See Figure X-1, above.

Table B-9 Medium Ramp Protocol Settings

Medium Ramp						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	1.0			
Exercise						
	1	0:30	1.5	3.0	End	End
	2	0:30	1.6	4.0	End	End
	3	0:30	1.7	5.0	End	End
	4	0:30	1.7	6.0	End	End
	5	1.00	1.8	7.0	End	End
	6	0:30	1.9	8.0	End	End
	7	0:30	2.0	8.5	End	End
	8	0:30	2.1	9.0	End	End
	9	0:30	2.2	9.5	End	End
	10	1.00	2.3	10.0	End	End
	11	0:30	2.4	11.0	End	End
	12	0:30	2.5	11.5	End	End
	13	0:30	2.6	12.0	End	End
	14	0:30	2.7	12.5	End	End
	15	1.00	2.8	13.0	End	End
	16	0:40	3.0	13.5	End	End
	17	0:40	3.2	14.0	End	End
	18	0:40	3.4	14.5	End	End
	19	0:40	3.6	15.0	End	End
	20	0:40	3.8	15.5	End	End
	21	0:40	4.0	16.0	End	End
	22	0:40	4.2	17.0	End	End
	23	0:40	4.5	18.0	End	End
	24	0:40	4.8	19.0	End	End
	25	0:40	5.2	20.0	End	End
Recovery						
	1	3:00	1.0	0.0	Every 02:00	Every 02:00

High Ramp Protocol

The Pre-Exercise phase settings are the same as for the Bruce protocol. See Figure X-1 on page X. The Recovery phase settings are the same as for the Medium Ramp protocol. See Figure X-8 on page Y.

Table B-10 High Ramp Protocol Settings

High Ramp						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	0:30	1.6	5.0	End	End
	2	0:30	1.7	10.0	End	End
	3	0:30	1.7	10.0	End	End
	4	0:30	2.0	10.0	End	End
	5	1.00	2.2	11.0	End	End
	6	0:30	2.4	11.5	End	End
	7	0:30	2.5	12.0	End	End
	8	0:30	2.6	12.5	End	End
	9	0:30	2.8	13.0	End	End
	10	1.00	3.0	13.5	End	End
	11	0:30	3.2	14.0	End	End
	12	0:30	3.4	14.0	End	End
	13	0:30	3.5	14.5	End	End
	14	0:30	3.6	15.0	End	End
	15	1.00	3.7	15.5	End	End
	16	0:40	4.0	16.0	End	End
	17	0:40	4.2	16.0	End	End
	18	0:40	4.4	16.5	End	End
	19	0:40	4.6	17.0	End	End
	20	0:40	4.8	17.5	End	End
	21	0:40	5.0	18.0	End	End
	22	0:40	5.2	19.0	End	End
	23	0:40	5.5	20.0	End	End
	24	0:40	5.8	21.0	End	End
	25	0:40	6.0	22.0	End	End
Recovery						
	1	3:00	1.0	0.0	Every 02:00	Every 02:00

USAF/SAM 2.0 Protocol

Table B-11 USAF/SAM 2.0 Protocol Settings

USAF/SAM 2.0						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	0.5	0.0	Off	Off
Exercise						
	1	3.00	2.0	0.0	End	Off
	2	3.00	2.0	5.0	End	End
	3	3.00	2.0	10.0	End	Off
	4	3.00	2.0	15.0	End	End
	5	3.00	2.0	20.0	End	Off
	6	3:00	2.0	25.0	End	End
Recovery						
	1	3.00	1.0	0.0	Every 02:00	Every 02:00

USAF/SAM 3.3 Protocol

Table B-12 USAF/SAM 3.3 Protocol Settings

USAF/SAM 3.3						
	Stage #	*Time Duration (mm:ss)*	*Speed (mph)*	*Grade (%)*	*ECG Print*	*BP Measurement*
Pre-Exercise						
	1	Unlimited	1.2	0.0	Off	Off
Exercise						
	1	3.00	3.3	0.0	End	Off
	2	3.00	3.3	5.0	End	End
	3	3.00	3.3	10.0	End	Off
	4	3.00	3.3	15.0	End	End
	5	3.00	3.3	20.0	End	Off
	6	3:00	3.3	25.0	End	End
Recovery						
	1	3.00	1.2	0.0	Every 02:00	Every 02:00

Cycle (Ergometer) Protocol

Table B-13 Cycle (Ergometer) Protocol Settings

Cycle (Ergometer)					
	Stage #	*Time Duration (mm:ss)*	*Power (Watts)*	*ECG Print*	*BP Measurement*
Pre-Exercise					
	1	Unlimited	10	Off	Off
Exercise					
	1	3.00	25	Begin	End
	2	3.00	50	Begin	End
	3	3.00	75	Begin	End
	4	3.00	100	Begin	End
	5	3.00	125	Begin	End
	6	3.00	150	Begin	End
	7	3.00	175	Begin	End
	8	3.00	200	Begin	End
	9	3.00	225	Begin	End
	10	3:00	250	Begin	End
Recovery					
	1	3.00	25	Every 01:00	Every 02:00

Astrand Protocol

Table B-14 Astrand Protocol Settings

Astrand					
	Stage #	*Time Duration (mm:ss)*	*Power (Watts)*	*ECG Print*	*BP Measurement*
Pre-Exercise					
	1	Unlimited	50	Off	Off
Exercise					
	1	6.00	50	End	End
	2	6.00	100	End	End
	3	6.00	150	End	End
	4	6.00	200	End	End
	5	6.00	250	End	End
	6	6.00	300	End	End
Recovery					
	1	3.00	50	Every 01:00	Every 02:00

C

Configuring and Using the Printer

The ST80i StressTest System supports the following different printers:

- ST80i thermal printer
- Network printer and local printer with Windows 7 drivers.

This appendix provides the following information:

For printer troubleshooting, see Appendix A, “Troubleshooting and Contacting the Response Center.”

ST80i Thermal Printer

The ST80i thermal printer uses an eight-dot-per-millimeter (dpm) print head to print ECG tracings and report data. Multiple print formats are supported.

The ST80i thermal printer includes:

- Hospital-grade power cord for connection to the isolation transformer
- USB cable for connection to the PC

Thermal Printer Dimensions and Specifications

Figure C-1 ST80i thermal printer dimensions

Figure C-2 ST80i thermal printer

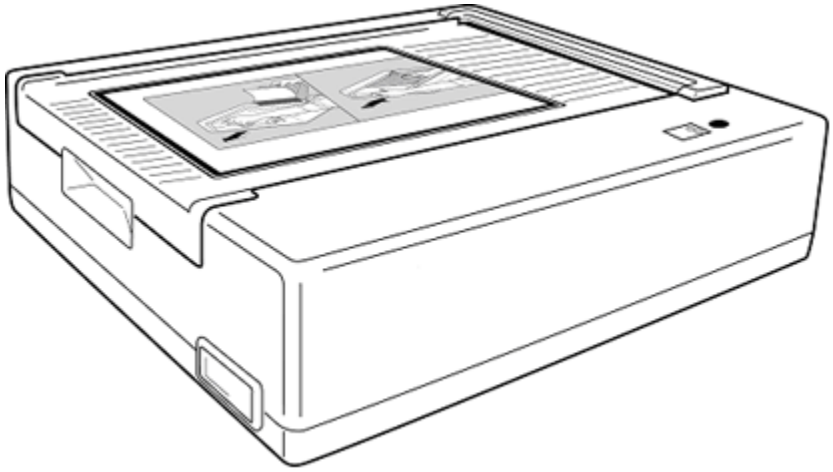


Table C-1 ST80i thermal printer specifications

Feature	Specification
Instrument type	Thermal printer
Paper type	Supports the use of the following paper types supplied as z-fold in packages of 100 and 200 sheets: ■ A-size Normal, Anti-fade, and Easy Tear ■ A4-size Normal, Anti-fade, thin, and Easy Tear
Recording technique	Computer controlled, thermal dot array
Print-head width	8.5 inches (216 mm)
Print-head resolution	■ Vertical: 200 dots/inch, vertical ■ Horizontal: 5, 10, and 25 mm/sec: 500 dots/inch 50 mm/sec: 250 dots/inch
Writer speeds	■ 25 or 50 mm/sec for AUTO report ■ 5, 10, 25, or 50 mm/sec for rhythm print
External ports and data interfaces	USB 2.0-compliant, type-B socket connector
Chassis leakage current	Meet or exceed requirements of ANSI/AAMI EC11
Power	100-240 VAC at 50/60 Hz
Weight	9 pounds
Dimensions H x W x D	8 cm x 48 cm x 30 cm maximum

Table C-1 ST80i thermal printer specifications

Feature	Specification
Fuses	T-Type 1 Amp, 250 V
Special functions	■ "Door closed" sensor that detects when paper door is open ■ "Top-of-form" sensor that positions paper at the edge and detects "paper out" and "paper jam" conditions

NOTE Specifications subject to change without notice.

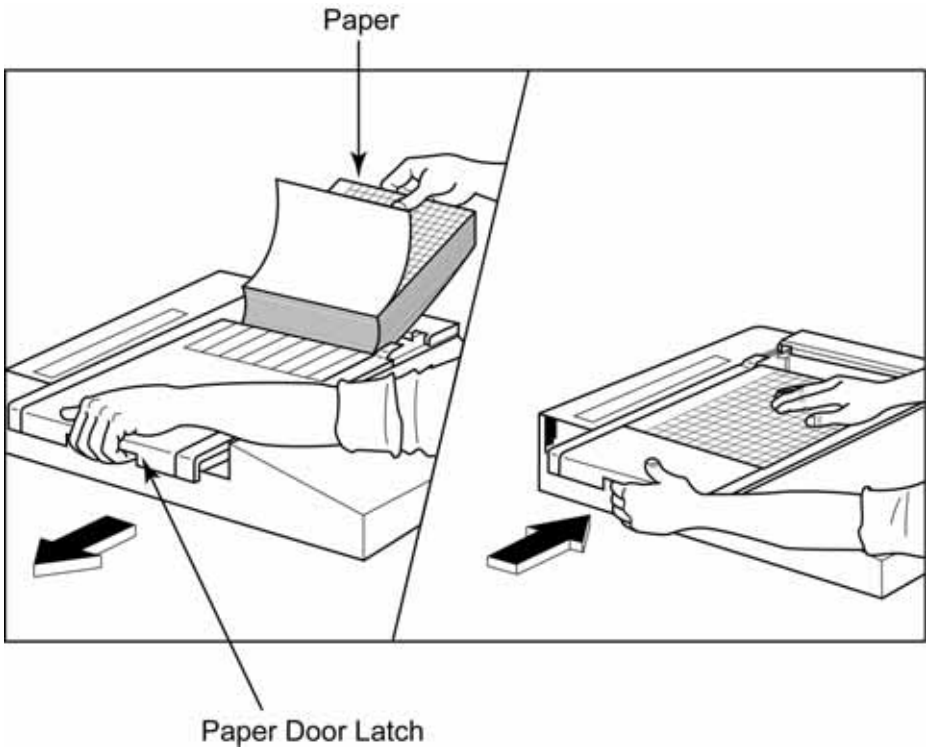
Table C-2 Input and Output descriptions

Feature	Description
AC Power	The ST80i thermal printer operates on 120/240 VAC at 50/60 Hz. Power is supplied to the thermal writer as soon as the AC power cord is connected to an AC power outlet.
Power On Indicator	This indicator will illuminate in green when AC power is applied.
Hard Copy Printout	The ST80i thermal printer uses 8 1/2 in x 11 in (21 cm x 27.9 cm) sheets of z-folded, thermal sensitive paper with cue marks. Printing speeds are 10, 25, and 50 mm per second. Dot density is eight dots per millimeter or 203.2 dpi.

Loading the Thermal Printer Paper

To load the paper

1. Remove the outer packaging from the paper pack.
2. Facing the front of the unit, use the release latch on the left side and slide the paper tray cover to the left.



3 Place the pack of thermal paper into the paper tray such that the grid side of the paper is up when it is pulled over the paper tray cover.

   The paper cue mark (a small black rectangle) should be in the lower left corner.

4 Manually advance one page of paper beyond the closure point of the writer.

   Make sure the paper lays on the black roller evenly within the channel of the paper door.

5 Slide the writer cover to the right until the cover latches in a locked position.

   You will hear a sharp click when the door is properly latched.

6 Push the form-feed button to align the cue mark and prepare the paper for printing.

Setting Up the Thermal Printer

To connect the ST80i thermal printer

1 Connect the AC power cord to the AC connector (**B**) on the printer and to an AC power outlet.

2 Connect one end of the crossover network cable to the network connector (**D**) on the ST80i thermal printer and the other end to the PCI card connector on the back of the ST80i PC, as shown in Figure C-3, below.

A Serial connector. Not used.

B AC connector (for power cord)

C AC fuses

D Integrated network (LAN) connector

Figure C-3 Connecting the thermal printer to the ST80i PC

About the Supported LaserJet Printers

ST80i also supports the use of the HP 4250 LaserJet, HP P2055, and HP P4014 PCL5 printers using drivers for the Windows 7 operating system.

It is capable of printing reports, without a grid, at 35 ppm. It prints with a grid at approximately 2 ppm.

NOTE The LaserJet printer must be a local printer, connected directly to the ST80i test system if it will be used during testing. It cannot be a network printer, as connection to the network is disabled during a test.

For details about the printers, refer to the HP website (www.hp.com) or to the printer documentation.

D

Ordering Options and Parts

This appendix describes the parts and options available for the ST80i Stress Test System.

This appendix provides the following information:

Supplies and Ordering Information

The part numbers for all supplies for the ST80i system are listed in this section.

All supplies may be ordered on the web at:

http://shop.medical.philips.com

Use the part numbers listed in the following tables for reference to ensure that the correct supplies are ordered.

Optional Parts and Accessories

For more information on accessories or to place an order, contact the nearest Philips Response Center. See “Philips Healthcare Customer Care Solution Center” on page A-8.

For available support parts (which can only be ordered by Philips personnel), see “Support Parts” on page D-3.

Part Number	Description
Lead Set Supplies	
989803180121	Leadset, 12L AAMI, Grabbers
989803180131	Leadset, 12L IEC, Grabbers
989803180141	Leadset, 12L AAMI, Snaps
989803180151	Leadset, 12L IEC, Snaps
989803180161	Leadset Long, 12L AAMI, Grabbers
989803180171	Leadset Long, 12L IEC, Grabbers
989803180181	Leadset Long, 12L AAMI, Snaps
40493E	Adult Foam ECG Electrode, Disposable

Support Parts

For more information on accessories or to place an order, contact the nearest Philips Response Center. See “Philips Healthcare Customer Care Solution Center” on page A-8.

The parts listed in the following tables can only be ordered by Philips personnel.

Exchange Part Number	New Assembly Part Number	Item
453564350261	453564277261	STRS ST80i Wireless PIM - AAMI
453564350251	453564277271	STRS ST80i Wireless PIM - IEC
453564350271	453564305221	STRS ST80i Advanced Input Module - AIM
453564032511	453564236991	STRS, ANT, AIM Antenna
453564350281	453564305231	STRS ST80i Thermal Printer

New Assembly Part Number	Item
PIM	
453564237251	STRS MECHASY Battery Door Assy
453564236601	PIM holder
453564236591	STRS, PIM Belt
AIM	
453564312961	STRS, AIM Box Mounting Bracket
453564236761	STRS, CBL, AIM Analog Out
USB	
453564096291	USB Cable AIM to PC 1m
453564336341	USB Cable Printer to PC 1.8m
Printer Accessories and Thermal Printer Paper	
453564048431	PW, PL, Metric Spacer, A4 paper
	Thermal PrinterPaper
Power Cords	
8120-1351	CBL AC POWER CORD 2 METER OPTION 900
8120-1689	CBL AC POWER CORD 2 METER OPTION 902
8120-2961	CMS CBL EXT GND ASSY(Crocodile clip)
8120-4211	CBL AC POWER CORD 2 METER OPTION 917
8120-4475	CBL AC POWER CORD 2 METER OPTION 901
8120-4933	CBL OPT-912 16-AWG 3-COND
8120-5182	CBL AC POWER CORD 2 METER OPTION 919
8120-6869	CBL AC POWER CORD 2 METER OPTION 920
8120-6978	CBL PWR-CORD-921 18-AWG 3-COND
8120-8376	CBL AC POWER CORD 2.2 METER OPTION 922
8120-5429	CBL AC 3 WIRE POWER CORD

New Assembly Part Number	Item
Trolley Parts	
453564237601	ST80i isolation transformer. - 240V
453564237591	ST80i isolation transformer. - 120V
453564334341	FUSE 6.30A 250V IEC
453564334331	FUSE 3.15A 250V IEC
453564315971	LAMP Trolley 220V
453564315961	STRS LAMP Trolley 120V
453564334151	STRS CASTER Roll Stand 4" TENTE
453564334161	STRS CASTER Roll Stand 4" TENTE Locking
453564334901	STRS PLAST Trolley Base Cover
453564334981	STRS PLAST Trolley Column Rear Cover
453564335001	STRS PLAST Trolley Wall Channel Cover
453564334881	STRS MET Basket Paper Catch
453564336361	Desk Light Power cord
453564336311	USB to RS232 Serial Adapter
453564334931	STRS PLAST Trolley Drawer Carriage
453564334941	STRS PLAST Trolley Basket Holder
453564334951	STRS PLAST Trolley Mushroom Mount
453564334961	STRS PLAST Trolley Cable Cover
453564334791	STRS MET Trolley Storage Shelf
453564334801	STRS MET Trolley Paper Basket
453564335281	STRS Utility Basket
453564335261	STRS MET Laser Printer Shelf W/Bracket
453564335261	STRS MET Top Shelf Utility Hook
453564335271	STRS 1/2 work surface cover
453564334881	STRS Basket Paper Catch
453564337261	STRS Full cover work surface

New Assembly Part Number	Item
453564312961	STRS, AIM Box Mounting Bracket
453564335301	STRS Tango Arm Kit
453564335271	STRS Utility Hook
Software and Documentation	
453564xxxxxx	*ST80i software CD*
453564xxxxxx	*ST80i Documentation and Training* CD

E

Specifications and Requirements

For details about setting up the system, see the *ST80i Installation and Configuration Guide*.

NOTE No user serviceable parts are inside. ANY modification of this device may alter defibrillator protection. Any modification to any part of this device is to be performed only by qualified service personnel. See also Chapter 5, “Maintaining the ST80i System”

This appendix provides the following information:

ST80i System Requirements

For the ST80i System to function properly, the following minimum specified system requirements must be met.

TIP For the latest information on supported systems and requirements, visit the Philips website listed below and select the Cardiology product line. The ST80i documentation and Technical Data Sheet containing the latest specifications are available online.

www.medical.philips.com/goto/productdocumentation

Table E-1 Minimum ST80i system requirements

Component	Minimum Hardware/Software Specifications
Processor	Intel® Core™ i5-2400S (2.50 GHz, 6 MB cache, 4 cores)
Memory	4GB 1333 MHz DDR3 SDRAM
Hard disk	No less than 160 GB SATA; 7200 RPM
Display	The lowest resolution for each layout: ■ For 4:3, the lowest resolution is 1024 x768 ■ For 16:9, the lowest resolution is 1280 x720 **NOTE** The display used with ST80i must meet UL/IEC 60950-1 Safety Standards for Information Technology Equipment.
Network	■ The PC's LAN interface should support IEEE 802.3 compliant 10M/100M/1000M Base-T(X) Ethernet connections ■ LAN connection for laser printer is required ■ Optional LAN card for networking capabilities
CD-ROM drive	CD-RW/DVD combo drive
Operating system	Microsoft Windows 7 Professional
External Connectivity	The system must have the following external connections: ■ RS232-USB bridge ■ 100-240V 50/60Hz AC Power input ■ Display output ■ LAN ■ Minimum of five (5) USB ports. ST80i may use an external USB hub to extend the USB ports for easier user access, if required. ■ Speaker output ■ Printer port.

Specifications

ST80i System Specifications

CAUTION The system does not contain user-serviceable parts. Any modification of this device may alter defibrillator protection. Only qualified service personnel are authorized to modify any part of this device.

Table E-2 ST80i system specifications

Function	Specifications
Instrument type	Exercise stress test system
Isolation transformer power	Rated Input/Output Voltage: 120 VAC @ 50/60 Hz Rated Input/Output Voltage: 240 VAC @ 50/60 Hz
Input Channels	Simultaneous acquisition of all 12 leads
Standard leads	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Exercise equipment interface	Digital serial interface to treadmill or ergometer
Automatic blood pressure measurement option	Supports optional SpO2 and motion tolerant NIBP modules.
Network option	Optional Network interface for data transfer and printing across your local network
Remote Review Workstation option	Optional Remote Review Workstation for review, printing, and editing of patient text data acquired from the ST80i system.
Display format	Sweep speed. Two supported speeds: 25 mm/s and 50 mm/s Size Range from 19" to 24" Resolution. The lowest resolution for each layout: For 4:3, the lowest resolution is 1024x768 For 16:9, the lowest resolution is 1280x720
ECG input	Simultaneous input from all 12 leads
Input impedance	■ Meets the requirements of ANSI/AAMI EC-11 ■ Defibrillator protected when used with specified patient cable
Input dynamic range	Meets the requirements of ANSI/AAMI EC-11

Table E-2 ST80i system specifications

Function	Specifications
Common mode rejection	Meets the requirements of ANSI/AAMI EC-11
Patient leakage current	Meets the requirements of ANSI/AAMI ES-1
Overall system error	Meets the requirements of ANSI/AAMI EC-11
Frequency response	Meets the requirements of ANSI/AAMI EC-11 Methods A and D were used to establish frequency response.
Digital sampling rate	1,000 sample/sec/channel, used for recording and analysis
Recording technique	■ Thermal array printer, 200 dots per inch (dpi)
Paper type	■ Thermal, perforated, 8.5 in x 11 in Z-fold
Recorder	Recording speeds. 5mm/sec, 10mm/sec, 25mm/sec, 50mm/sec Channels. User can select any channels to print on thermal printer Sensitivity. 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV Gain 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV Data acquisition Direct connect or wireless connection using ST80i wireless patient interface module
Max Power Rate Consumption	Computer. 180 W Monitor. 50 W Thermal printer. 60 W NIBP/SPO2 module 45 W 19"/24" Display 50 W Desk light 5.5 W USB Hub TBD Isolation Transformer. 600 Volt Amps Treadmill TBD
Device Classification	Class 1, Type CF defibrillator-proof applied parts
Data acquisition	Direct connect or wireless connection using ST80i digital transmitter
External output	TTL and analog output

Medical Isolation Transformer Specifications

The medical isolation transformers used with the ST80i system meet the following specifications: UL 60601-1, CSA C22.2 601.1, EN60601.1, CE (LVD), ROHS compliant.

Figure E-1 Medical isolation transformer provided with ST80i

Table E-3 Medical isolation transformer specifications

Function	Specifications
Frequency	50/60 Hz
Output ratings	120V 600VA or 240V 600VA
Weight	26.5 lb (12 Kg)
Dimensions	Height. 4.08" (103.5mm) Width. 6.55" (166.4mm) Depth. 10.5" (266.7mm)
REF: 1404-102	Input 120VAC – 6.3AT
REF: 1404-003	Input 230VAC – 3.15AT.
Fuses	Use agency-approved fuses only, 250V. The transformer has an internal thermal resettable fuse.

ST80i Thermal Printer Specifications

Table E-4 ST80i thermal printer specification

Feature	Specification
Instrument type	Thermal printer
Paper type	Supports the use of the following paper types supplied as z-fold in packages of 100 and 200 sheets: ■ A-size Normal, Anti-fade, and Easy Tear ■ A4-size Normal, Anti-fade, thin, and Easy Tear
Recording technique	Computer controlled, thermal dot array
Print-head width	8.5 inches (216 mm)
Print-head resolution	■ Vertical: 200 dots/inch, vertical ■ Horizontal: 5, 10, and 25 mm/sec: 500 dots/inch 50 mm/sec: 250 dots/inch
Printer speeds	■ 25 or 50 mm/sec for AUTO report ■ 5, 10, 25, or 50 mm/sec for rhythm print
External ports and data interfaces	USB 2.0-compliant, type-B socket connector
Chassis leakage current	Meet or exceed requirements of ANSI/AAMI EC11
Power	100-240 VAC at 50/60 Hz
Weight	9 pounds
Dimensions H x W x D	8 cm x 48 cm x 30 cm maximum

Supported Treadmills and Ergometers

The ST80i Stress Test System supports the following treadmills and ergometers.

Table E-5 Supported Treadmills and Ergometers

Equipment	Manufacturer	Models
Treadmills	Trackmaster Treadmills by Full Vision	■ FVX328 ■ FVX328C ■ FVX328CP ■ TMX425 ■ TMX425C ■ TMX425CP
Ergometers	Ergoline	■ Ergometer Type er800S ■ Ergometer Type er900 ■ Ergometer Type er900EL ■ Ergoselect Reha ■ Ergoselect 600 (recumbentbike, ergometer)
	Lode	■ Angio ■ Corival ■ Excalibur Sport

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the ST80i Stress Test System and optional Thermal Printer.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the ST80i Stress Test System and optional Thermal Printer according to the international standard for EMC for medical devices (IEC 60601-1-2 Edition 2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2 Edition 2).

The ST80i Stress Test System and optional Thermal Printer should not be used adjacent to, or stacked on top of, other equipment. If the ST80i Stress Exercise Testing System and optional Thermal Printer must be used adjacent to or stacked on top of other equipment, verify that the

ST80i Stress Test System and optional Thermal Printer operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See Table E-9, “Recommended Separation Distances,” on page E-14 for recommended separation distances between the radio equipment and the ST80i Stress Exercise Testing System and optional Thermal Printer.

Accessories and Cables Warning

The use of accessories and cables other than those specified in Appendix F, “Ordering Options and Parts” may result in increased emissions or decreased immunity of the ST80i Stress Test System and optional Thermal Printer.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The ST80i Stress Test System and optional Thermal Printer are intended for use in the electromagnetic environment specified in the table below. The customer or the user of the ST80i Stress Test System and optional Thermal Printer should assure that it is used in such an environment.

Table E-6 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1 30 MHz to 1000 MHz	The ST80i Stress Test System and optional Thermal Printer use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B 150 kHz to 30 MHz	The ST80i Stress Test System and optional Thermal Printer are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Note** ST80i PIM and AIM are designed and certified to meet CFR 47 FCC Part 15 and EN 301 489 for devices with intentional transmitters.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The ST80i Stress Test System and optional Thermal Printer are intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the ST80i Stress Test System and optional Thermal Printer should assure that it is used in such an environment.

Table E-7 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact discharge +/- 8 kV air discharge	+/- 6 kV contact discharge +/- 8 kV air discharge	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 line +/- 1 kV for input/ output	+/- 2 kV for power supply line +/- 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 differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	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% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ST80i Stress Test System and optional Thermal Printer requires continued operation during power mains interruptions, it is recommended that the ST80i Stress Test System and optional Thermal Printer be powered from an uninterruptible power supply or a battery.

Table E-7 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field immunity	3 A/m, 50 & 60 Hz	3 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the AC mains voltage prior to application of the test level.

Table E-8 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted Immunity, Induced RF IEC 61000-4-6	*3Vrms*, 0.15 MHz to 80 MHz, @ 10 Hz AM	*3Vrms*, 0.15 MHz to 80 MHz, @ 10 Hz AM	Portable and mobile RF communications equipment should be used no closer to any part of the ST80i Stress Test System and optional Thermal Printer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	General Test: 3V/m, 80 MHz to 2.5 GHz @ 10 Hz AM Digital Radio Test: 3V/m 80% AM @ 1kHz , 800 MHz to 960 MHz , 1.4 GHz to 2.5 GHz	General Test: 3V/m, 80 MHz to 2.5 GHz @ 10 Hz AM Digital Radio Test: 3V/m 80% AM @ 1kHz , 800 MHz to 960 MHz , 1.4 GHz to 2.5 GHz	$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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: 

Table E-8 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electro-surgery Interference IEC 60601-2-25	100W & 300W Cut/Coag, at 450 kHz ± 100 kHz.	100W & 300W Cut/Coag, at 450 kHz ± 100 kHz.	

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 ST80i Stress Test System and optional Thermal Printer are used exceeds the applicable RF compliance level above, the ST80i Stress Test System and optional Thermal Printer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ST80i Stress Test System and optional Thermal Printer.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended Separation Distances

The ST80i Stress Test System and optional Thermal Printer are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ST80i Stress Test System and optional Thermal Printer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ST80i Stress Test System and optional Thermal Printer as recommended below, according to the maximum output power of the communications equipment.

Table E-9 Recommended Separation Distances

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)	
	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4.0 m	7.0 m
100	12.0 m	23.0 m

NOTES

- 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.
- At 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

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Instructions for Use

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