

Welch Allyn Remote Monitoring Scale RPM-Scale100



Directions for use

901077 Weight scale, Software Version 1.0

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www.welchallyn.com/about/company/locations.htm.

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This manual applies to REF 901077 Weight scale.

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Introductory information

Introduction

The Welch Allyn Remote Monitoring Scale is intended for adults and children (10-17 years old) to measure weight in a home environment.

This Directions for use contains important safety and care information and provides step by step instructions for using the scale. Read the manual thoroughly before using the scale.

For information about any Welch Allyn product, contact your local Welch Allyn representative at www.welchallyn.com/about/company/locations.htm.

Indications for use

The Welch Allyn Remote Monitoring Scale is intended for adults and children (10–17 years old) to measure weight in home.

Contraindications

This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.

Symbols

Documentation symbols



Warning: The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning symbols will appear with a grey background in a black and white document.



Caution: The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.






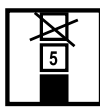


Mandatory - Consult Directions for Use


Power symbols

	Direct current (DC)
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


Shipping, storing, and environment symbols

	Humidity limitation		Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.
	Temperature limit		Atmospheric pressure limitation
	Recycle		Stacking limit by number

Connectivity symbols

	Bluetooth® wireless technology enabled
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Miscellaneous symbols

	Serial number		Manufacturer
	Product identifier, product family catalogue number		Non-ionizing electromagnetic radiation
	Reorder number, Model number		Global Trade Item Number
IP22	The ingress protection: the device could protected against solid foreign objects of 12.5mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°		Type BF applied parts

About warnings and cautions

Caution statements can appear on the Welch Allyn weight scale device, the packaging, the shipping container, or in this Directions for use.

The Welch Allyn weight scale is safe for patients and clinicians when used in accordance with the instructions and caution statements presented in this Directions for use.

Before using the device, you must familiarize yourself with all cautions, with the steps to power up the device, and with the sections of this Directions for use that pertain to your use of the device. In addition to reviewing the general cautions presented in the next section, you must also review the more specific cautions that appear throughout the manual in conjunction with setup/startup, operation, and maintenance tasks.

- Failure to understand and observe any warning statement in this manual could lead to patient injury or illness.
- Failure to understand and observe any caution statement in this manual could lead to damage to the equipment or other property, or loss of patient data.

General warnings and cautions



Warning Patient injury risk. Do not use the scale on a slippery floor, such as tile.



Warning Patient injury risk. Do not jump onto the platform immediately after bathing or with wet hands.



Warning Patient injury risk. Keep the device clean. Patient contact with contaminated equipment can spread infection. Clean the device after each patient use.



Warning Patient injury risk. Dispose of accessories, detachable parts, and the ME equipment according to the local guidelines.



Warning Patient injury risk. The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.



Warning Patient injury risk. No modification of this equipment is allowed. Modifying the equipment could cause patient injury.



Warning Patient injury risk. Do not touch output of the batteries and the patient simultaneously.



Warning Patient injury risk. Before use, make sure the device functions safely and is in proper working condition.












Warning Patient injury risk. When the scale is in use, there should not be any electrical appliances nearby, such as high voltage cables, X-ray machines, or ultrasound equipment.



Warning Possible injury risk. The device contains small parts. Keep the equipment away from children and pets.



CAUTION Avoid storing the device where the device may be exposed to extreme temperatures, humidity, moisture, direct sunlight, dust, or salt air.

-  CAUTION Avoid storing the device where there is risk of shock or dropping.
-  CAUTION Avoid storing the device where you store chemicals.
-  CAUTION Avoid storing the device where there are corrosive gases.
-  CAUTION Avoid storing the device near infants or children.
-  CAUTION The device does not need to be calibrated in two years of reliable service.
-  CAUTION Do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorized service centers.
-  CAUTION Manufacturer will make available on request circuit diagrams, component parts lists, and the like.
-  CAUTION Wireless communications equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkietalkies can affect this equipment and should be kept at least a distance $d=3,3\text{m}$ away from the equipment. Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME Equipment, a typical cell phone with a maximum output power of 2 W yields $d=3,3\text{m}$ at an IMMUNITY LEVEL of 3V/m).
-  CAUTION Do not use rechargeable batteries.

Ensure accurate measurements

To ensure the accuracy of measurements, follow the recommendations below when you start a measurement.

- Place the scale on a flat, hard surface. If you put the scale on carpet, fit the extension feet before taking the measurement. Placing the scale sensors directly on carpet may affect the accuracy of the measurement.
- Always start a measurement at the same time on the same scale located on the same flat surface.

Content list

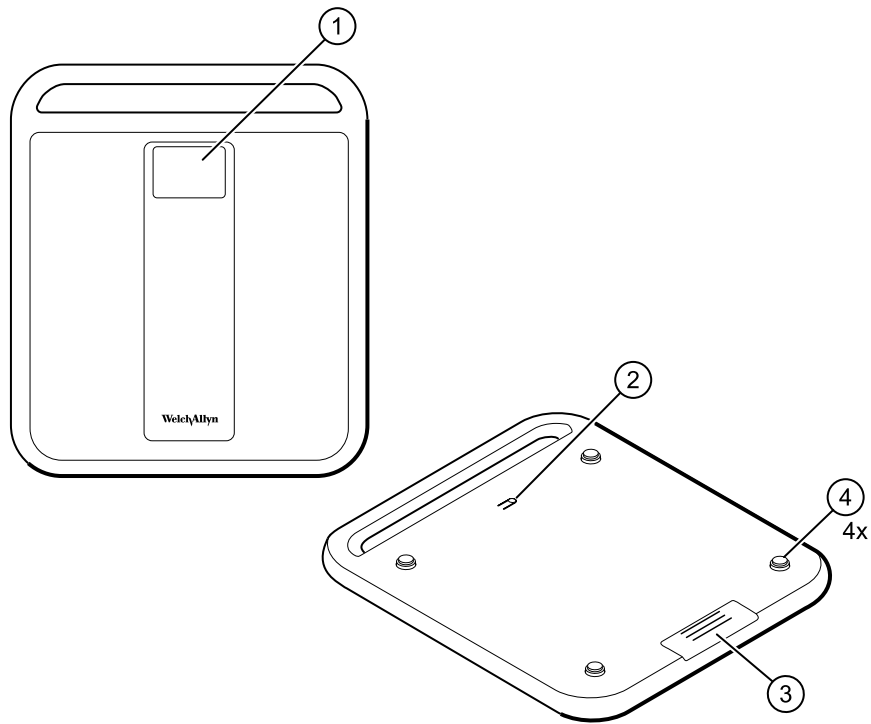
The following items are in the device box:

- Remote Monitoring Scale
- (4) AAA alkaline batteries (1.5V each)
- (4) extension feet for use on carpet
- Directions for use

Controls and indicators

The Welch Allyn weight scale is simple to use.

Scale top









No.	Feature	Description
1	LCD display	Displays measurement
2	UNIT and activation button	The button enables you to select kg or lb unit measure. Press and hold for 3 seconds to enter pairing mode.
3	Battery compartment (behind cover)	Houses (4) AAA alkaline batteries (1.5V each)
4	Sensors (4)	4 load cell sensors which conduct weight measurement

Screen elements

The liquid crystal display (LCD) display registers the measurement. The display also may show other icons that provide information about the functionality of the scale.



Icon	Description	Icon	Description
kg	Kilogram		Data transmitting
lb	Pound		Data pending to transmit to wireless wellness system
	Low battery charge		Full battery charge
	Bluetooth wireless technology is powered on		Bluetooth wireless technology connected (dotted area is not flashing)
	Data being transferred using Bluetooth wireless technology (dotted area flashes)		Scale not paired with device


Use the scale

Startup

The Welch Allyn weight scale uses SENSE ON™ technology to turn on the scale. Step on the scale with bare feet to begin a measurement.

Insert or replace the batteries



CAUTION When the  symbol appears, the device will power off in four seconds. Replace the old batteries with a new set of four batteries. Always replace all four batteries with new batteries. Do NOT mix old batteries with new batteries



CAUTION Remove the batteries if the device is not to be used for some time.



CAUTION Dispose old batteries by following your local recycling guidelines.



CAUTION Do not burn batteries. Batteries may leak or explode.

1. Open the battery door on the under side of the scale.
The digits "8888" appear on the LCD screen.
2. Insert the four AAA alkaline batteries (1.5V each) into the battery compartment according to the polarity indications marked inside the battery compartment.
3. Close the battery door.
4. Wait until the digits "0.0lb" appear on the LCD screen.



Pair a connection hub with the scale

With advanced Bluetooth 4.0 Technology applied, a communication hub is capable of receiving your personal health data. Contact your Remote Patient Monitoring Solution provider for connectivity instructions and troubleshooting.

1. Confirm that both the connection hub and the weight scale are powered on.

Note Bluetooth wireless connectivity is only available for devices which support Bluetooth 4.0 technology.

2. Press and hold the Unit button on the bottom of the scale for 2 seconds.
The Bluetooth pairing sequence is activated. The dotted line surrounding the Bluetooth symbol flashes while discovering the weight scale.

If successful, a steady  symbol surrounded by a dotted line appears on the scale's LCD screen. If unsuccessful, the  appears.

Select the measurement unit

The default measurement unit is pound (lb).

Press the Unit button on the bottom of the scale to change from pound (lb) to kilogram (kg).

Obtain measurement

With the original SENSE ON patent technology, the scale automatically powers on when you step on the platform in your bare feet.

1. Step on the platform in your bare feet.
The scale automatically powers on and begins the measurement.
2. Stand still and keep full contact with the scale until the LCD stops blinking and displays the weight.

Stop a measurement

You can stop a measurement before it is complete.

Step off the platform.

The scale returns to a ready / zero state.

After approximately 2 seconds, the scale powers down automatically.

Maintain the scale



Warning Patient injury risk. Keep the device clean. Patient contact with contaminated equipment can spread infection. Clean the device after each patient use.

Clean on a routine basis according to facility protocols and standards or local regulations.

Disinfect according to facility protocols and standards or local regulations.


The following agents are compatible with the device:

- CaviWipes or Sani-Cloth Plus
- 70 percent isopropyl alcohol
- 10 percent chlorine bleach/90 percent water solution

Troubleshooting

This section includes a list of error messages and frequently asked questions for problems you may encounter with your weight scale. If the device is not operating as you think it should, check here before arranging for servicing.

Error prompt

Error	Description	Solution
Dotted lines	Overload. The device will power off	Stop using this scale for measurement
	Low Battery. The device will power off in four seconds.	Replace all four batteries at the same time. Purchase the authorized batteries for replacement.
Error condition	At any point, when a situation occurs that prevents a successful test acquisition, an error code will be displayed in the LCD area. The message will persist for several seconds until the device times out and powers down.	Check the following items: <ul style="list-style-type: none"> • Bluetooth wireless technology is on. • The application is on. • Both devices are within the transmission distance of Bluetooth devices.

When measuring

Problem	Root cause	Solution
No display on the LCD screen with the scale powers on	Batteries are not installed or not installed properly	Install the batteries. Go to "Insert or replace the batteries"
	Worn batteries	Replace all four batteries at the same time. Purchase the authorized batteries for replacement.
The scale powers off automatically	Low Battery.	Replace all four batteries at the same time. Purchase the authorized batteries for replacement.

When transmitting data

Problem	Root cause	Solution
Data transmission failed	Bluetooth wireless technology is off	Turn on the Bluetooth wireless technology via the Settings.
	Application is off	Press the icon to run your application.
	Out of range of Bluetooth transmission.	Place your mobile or portable device closer to the scale.

Appendices

Specifications

Warning: No modification of this equipment is allowed.

Item	Specification
Power supply	6V 4*AAA alkaline batteries
Display mode	Blue LCD with White Backlight V.A.: 74x53mm
Measurement unit	Kilogram / Pound
Measurement range	5kg to 200kg / 11lb to 441lb
Resolution	The measurement resolution shall be: 0–100kg: 0.1kg 100–200kg: 0.2kg <hr/> 100-150kg: ±0.5kg; 150-200kg: ±0.7kg
Normal working condition	Temperature: 5 to 40 Humidity: 85%RH <hr/> Atmospheric pressure: 86kPa to 106kPa
Division	0.1kg / 1.2lb
Storage & transportation condition	Temperature:-20 to 60 Relative Humidity: 10% RH–93% RH <hr/> Atmospheric Pressure: 50kPa to 106 kPa
Net Weight	Approximately 1.98kg (Excluding the dry cells)
Dimensions	360mm x 408mm x 32.5mm with carpet feet
Accessories	<ul style="list-style-type: none"> • (4) AAA alkaline batteries • (4) extension feet • Directions for use

Item	Specification
Mode of operation	Continuous operation
Auto-ON	SENSE ON technology
Auto-OFF	About 10 seconds when showing 0.0 About 15 seconds after the weight data is locked
Degree of protection	Type BF applied part
Protection against ingress of water	IP22
Software Version	Version 1.0

General radio compliance

Item	Specification
Bluetooth Module No.	AW8001
RF Frequency Range	2402 MHz to 2480 MHz
Output Power Range	-2.27dBm to -5.88 dBm
Supply Voltage	1.8-3.6 V
Antenna Gain	1.0dBi
Transmitting Distance	10 meters, (30 feet)

Federal Communication Commission (FCC) Interference Statement

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.

This equipment (FCC ID: OU9BS-1507) has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency 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 equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures.

- 1.Reorient or relocate the receiving antenna.

2. Increase the separation between the equipment and receiver.
3. Consult the dealer or an experienced radio/TV technician for help.

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

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Industry Canada (IC) compliance

To ensure compliance with FCC and Industry Canada RF exposure requirements, this device must be installed in a location where the antennas of the device will have a minimum distance of at least 20 cm from all persons. Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Installez l'appareil en veillant à conserver une distance d'au moins 20 cm entre les éléments rayonnants et les personnes. Cet avertissement de sécurité est conforme aux limites d'exposition définies par la norme CNR-102 relative aux fréquences radio.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (IC ID: 12725A-BS1507) has been approved by Industry Canada to operate with the antenna listed in the specification table.

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

Complied standards list

Item	Standard
Risk management	ISO/EN 14971 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements Tested in accordance with ISO 10993 Biocompatibility

Item	Standard
User manual	EN 1041 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1+A1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Software life-cycle processes	IEC/EN 62304+AC Medical device software - Software life cycle processes
Usability	IEC 62366 Medical devices - Application of usability engineering to medical devices (IEC 62366) IEC 60601-1-6 Medical electrical equipment - Part 1 -6 : General requirements for basic safety and essential performance - collateral standard : Usability

Emissions and immunity information

The Welch Allyn Remote Monitoring Scale RPM-SCALE100 is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn Remote Monitoring Scale RPM-SCALE100 should assure that it is used in such an environment.

This equipment needs to be installed and put into service in accordance with the information provided in the user manual.



CAUTION Wireless communications equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkie can affect this equipment and should be kept at least a distance $d=3,3m$ away from the equipment.

Note As indicated in Table 6 of IEC 60601-1-2:2007 for ME Equipment, a typical cell phone with a maximum output power of 2 W yields $d=3,3m$ at an IMMUNITY LEVEL of 3V/m).

Electromagnetic emissions

The Welch Allyn Remote Monitoring Scale RPM-Scale100 is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn Remote Monitoring Scale RPM-Scale100 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
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Electromagnetic emissions

RF emissions CISPR 11	Group 1	The Welch Allyn Remote Monitoring Scale RPM-Scale100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Welch Allyn Remote Monitoring Scale RPM-Scale100 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity

The Welch Allyn Remote Monitoring Scale RPM-Scale100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn Remote Monitoring Scale RPM-Scale100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV differential 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	<5% U _T (>95% dip in U _T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Welch Allyn Remote Monitoring ScaleRPM-Scale100 requires continued operation during power mains interruptions, it is recommended that the Welch Allyn Remote Monitoring Scale RPM-Scale100 be powered from an uninterruptible power supply or a battery.
	40% U _T (60% dip in U _T) for 5 cycles	40% U _T (60% dip in U _T)for 5 cycles	
	70% U _T (30% dip in U _T) for 25 cycles	70% U _T (30% dip in U _T) for 25 cycles	
	<5% U _T (>95% dip in U _T) for 5 seconds	<5% U _T (>95% dip in U _T) for 5 seconds	

Electromagnetic immunity

Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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Note: U_T is the AC mains voltage prior to application of the test level.

Electromagnetic immunity

The Welch Allyn Remote Monitoring Scale RPM-Scale100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn Remote Monitoring Scale RPM-Scale100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn Remote Monitoring Scale RPM-Scale100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = (1.167) \sqrt{P}$
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Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz	3 V/m	$d = (1.167) \sqrt{P}$ 80 to 800 MHz
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$$d = (2.333) \sqrt{P} \text{ 800 MHz to 2,5 GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) 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:



Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Welch Allyn Remote Monitoring Scale RPM-Scale100 is used exceeds the applicable RF compliance level above, the Welch Allyn Remote Monitoring Scale RPM-

Electromagnetic immunity

Scale100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Welch Allyn Remote Monitoring Scale RPM-Scale100.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn Remote Monitoring scale RPM-SCALE100

The Welch Allyn Remote Monitoring Scale RPM-Scale100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Welch Allyn Remote Monitoring Scale RPM-Scale100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn Remote Monitoring Scale RPM-Scale100 as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)

Rated max. output power of transmitter (W)	150 kHz to 80 MHz $d = (1.167) \sqrt{P}$	80 MHz to 800 MHz $d = (1.167) \sqrt{P}$	800 MHz to 2.5 GHz $d = (2.333) \sqrt{P}$
0.01	0.167	0.167	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.690	3.690	7.338
100	11.67	11.67	23.33

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

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

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

Warranty

Welch Allyn will warranty the Transtek weight scale to be free of defects in material and workmanship and to perform in accordance with manufacturer specifications for the period of two years from the date of retail purchase.

The warranty period shall start on the date of purchase. The date of purchase is: 1) the invoiced ship date if the device was purchased directly from Welch Allyn, 2) the date specified during product registration, 3) the date of purchase of the product from a Welch Allyn authorized distributor as documented from a receipt from said distributor.

This warranty does NOT cover damages caused by misuse or abuse, including but not limited to:

- Failure caused by unauthorized repairs or modifications
- Damage caused by shock or dropping during transportation

- Damage caused by improper use of the power supply
- Failure caused by improper operation not consistent with the instructions stated in this Directions for use

Should this device require maintenance (or replacement at our option) under warranty, please deliver the original package to Welch Allyn prepaid. Please return the store receipt (with the retail purchase date) and a note with the reasons for the return.

Approved accessories

Item	Description
RPM-SCALEACC-01	Carpet Feet 40EA

