

Hillrom_™ Welch Allyn[®] CareTemp[™] Touch-Free Thermometer



Instructions for use

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This manual applies to # 901094 Non Contact Thermometer.

EC REP

Medical Device Safety Service GmbH Schiffgraben 41, D-30175 Hannover, Germany





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Symbols

Documentation symbols



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.



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. This definition applies to both yellow and black and white symbols.



Consult operating instructions for use (IFU).



Meets essential requirements of European Medical Device Directive 93/42/EEC.

A copy of the IFU is available on this website.

A printed copy of the IFU can be ordered from Hillrom for delivery within 7 calendar days.

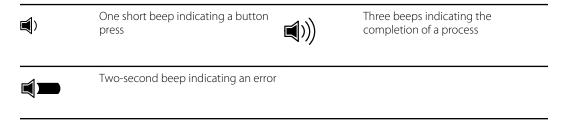
Shipping, storing, and environment symbols

-13°F -25°C	Temperature limits	Ť	Keep dry
X	This device shall be disposed of in accordance with national laws after its useful life.	Ţ	Fragile
55% 15%	Humidity limitation	IP22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (IP22: Protection level against solid foreign objects and falling water)

Miscellaneous symbols

	Manufacturer	REF	Reorder/Catalog number
#	Product identifier	EC REP	European authorized representative
GTIN	Global trade identification number	SN	Serial number
ETL CLASSIFIED C Intertek 4010674	Conforms to AAMI STD ES 60601-1, IEC STD 60601-1-6, ISO STD 80601-2-56; Certified to CSA STD C22.2 NO. 60601-1, NO. 60601-1-6, No. 80601-2-56	†	Type BF applied part
R _x only	By prescription or order of licensed healthcare professional		

Indicator symbols



Battery level indicators

100 to 76 percent of useable battery capacity remaining Approximately 3,300 measurements	75 to 51 percent of useable battery capacity remaining Approximately 1,900 measurements
50 to 26 percent of useable battery capacity remaining Approximately 880 measurements	25 to 11 percent of useable battery capacity remaining Approximately 200 measurements
10 to 0 percent of useable battery capacity remaining When the battery flashes, no measurements can be taken	

Introduction

Intended use

The CareTemp™ Touch Free thermometer is a clinical-grade device intended for the intermittent measurement of human body temperature in patients of all ages in a professional-use environment.

General warnings and cautions

Warning and caution statements can appear on the thermometer, the packaging, the shipping container, or in this document.

The thermometer is safe for patients and clinicians when used in accordance with the instructions and with the warning and caution statements presented in this manual.

Before using the thermometer, familiarize all operating personnel with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual.

- Failure to understand and observe any warning statement in this manual could lead to patient illness, injury, or death.
- 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.



WARNING Patient safety. The thermometer is designed for the intermittent measurement of the human body's temperature, and can be used upon people of all ages. The following recommendations must be carefully observed during the product's use. Any activities that are inconsistent with or do not take into account these recommendations could result in personal injury or could affect the accuracy of the thermometer itself.



WARNING Patient safety. If the accuracy of any measurement is in question, check the patient's temperature with an alternate method and then check to verify the device is functioning properly.



WARNING Safety risk. The thermometer battery must be kept strictly out of the reach of children, as ingestion of the battery could result in poisoning or other serious health risks.



WARNING Safety risk. Always dispose of batteries in accordance with applicable legal regulations.



CAUTION Always use new batteries of the type and specification indicated in this manual. Mixing old and new batteries will shorten the battery life.



CAUTION Do not use rechargeable batteries, as these may be of inferior quality and duration. The use of rechargeable batteries could compromise the performance of this device.



CAUTION Leaking batteries can damage the device. Remove the batteries whenever the device is not expected to be used for an extended period of time (e.g. multiple months).



CAUTION If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.



CAUTION Federal US law restricts sale of the device identified in this manual to, or on the order of, a licensed healthcare practitioner



CAUTION Proper measurement distance between 4 and 6 cm from the patient's forehead is essential to the accuracy of the temperature measurement determination.



CAUTION Unauthorized modifications to the device are not permitted. Do not modify the product in any way without the manufacturer's prior authorization.



CAUTION In order to avoid incorrect measurements, make sure that the lens on the thermometer's infrared sensor lens is clean and intact prior to use.



CAUTION Avoid touching the infrared sensor lens directly with your fingers.



CAUTION Do not expose the thermometer to extreme temperatures or humidity levels. Make sure that you follow the instructions provided in this manual. Do not expose to direct sunlight.



CAUTION The thermometer is NOT waterproof.



CAUTION Avoid dropping the device.



CAUTION Do not autoclave. Follow only the cleaning procedures described in this manual.



NOTE Both the patient and the thermometer should be kept within the same environmental conditions for at least 30 minutes prior to each measurement.



NOTE Avoid taking temperature measurements for at least 30 minutes after physical activity, bathing, swimming, consuming food or beverages, or spending time outdoors.



NOTE Wait at least 1 minute between temperature measurements. Measurements performed too frequently could result in incorrect temperature readings.



NOTE Contact Welch Allyn or your local Welch Allyn representative for any assistance with configuration, use, and maintenance operations.



NOTE Avoid pointing the infrared sensor at any heat source other than a patient. This might affect patient measurements.



NOTE Avoid exposing the device to external heat sources. This might affect patient measurements.

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NOTE If possible, measurements should always be taken by pointing the infrared sensor at the same area of the forehead. Temperatures measured at different locations on the temples or on opposite sides of the head can vary considerably.

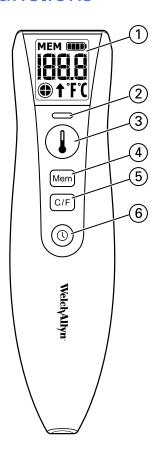


NOTE Holding the thermometer in your hands for too long or exposing the device to external heat sources could result in distorted temperature readings. For this reason, the body temperature reading could result as being higher or lower than the actual value.

Welch Allyn® CareTemp™ Touch Free Thermometer

Using the thermometer

Button functions



- 1. Display
- 2. LED bar
- 3. Measure

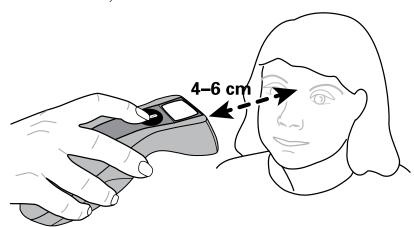
- 4. Memory
- 5. C/F (Celsius/Fahrenheit)
- 6. Pulse timer

Take a measurement

1. Press **Measure** to power on the thermometer.

When the device is ready, a single dash appears on the screen, and a beeps sounds.

2. Position the thermometer between 4 and 6 cm from the center of the patient's forehead, and aim between the eyebrows.





NOTE If the eyebrow area is covered with hair, sweat, or dirt, clean the area and wait 10 minutes to before taking a measurement.



NOTE Hold the thermometer and the forehead steady during measurement. Movement can impact the measurement.

3. Press **Measure**. **Slowly** move the device toward or farther from the forehead.

The arrow on the display flashes until the correct distance is achieved.



NOTE After pressing **Measure**, the thermometer allows 20 seconds to capture the measurement. If you press **Measure** again before the 20 second time limit is up, the process restarts. If the measurement is not completed in 20 seconds, the device displays **Err** ↑. Press **Measure** to restart the process.

4. When the correct distance is reached the LED bar will illuminate, three beeps sound, and the measurement is displayed.

To repeat the process, return to step 2.



NOTE The complete measurement or **Err** ↑ message displays for 3 seconds. After 3 seconds, the thermometer returns to ready.

5. The thermometer automatically turns off after 10 seconds of inactivity.

Instructions for use Using the thermometer 9

Recall a measurement

Pressing the Memory button (**MEM**) will display the temperature in memory with a MEM indicator. Memory is available directly from the off state, when no measurement is displayed, or immediately following a new measurement if a comparison to the prior reading is needed. Once the thermometer is powered off or a new measurement is initiated, the last temperature taken becomes the reading in memory.

1. Press and release **MEM**.

The LCD displays the temperature stored in the thermometer's memory for 10 seconds.

2. Press and hold **MEM** for 3 seconds to force the measurement on the display to memory and clear the display.

The thermometer beeps three times to indicate the measurement is moved to memory and the thermometer is ready to take a new measurement with a clear display.



NOTE It is not required to force a reading to memory. A new reading will automatically move to memory when the thermometer turns off or a new measurement is initiated.

Use the timer

1. Press and release the **Timer** button.

The timer is activated. Audible beeps sound at 0, 15, 45, and 60 seconds.

2. Press the **Timer** button again to exit at any time.

After the full 60 second cycle, the thermometer turns off automatically after 2 seconds.

Change the temperature scale

1. Press **C/F** to temporarily view the measurement in the alternate temperature scale.

This scale conversion feature is available any time a temperature value is displayed, and can be used to continuously alternate between temperature scales.

2. Press and hold both the **MEM** and **C/F** buttons for 3 seconds to change the default scale.

Three beeps sound to confirm the setting is changed.

The alternate scale remains until one of the following occurs, returning the thermometer to the default temperature scale:

- The C/F button is pressed again.
- A new measurement is taken.
- Any other action is taken.
- The thermometer turns off.

Troubleshooting and error messages

Error message displayed	Possible cause	Suggested action
Err	The thermometer distance to the patient is out of range	Take the measurement again, and make sure the thermometer is 4 to 6 cm away from the center of the patient's forehead, just between the eyebrows.
Егг	The ambient temperature of the room is outside the operating range of 60.8 °F to 104 °F (16 °C to 40 °C)	Move to a room with the proper ambient temperature and wait 30 minutes for the thermometer to stabilize.
Lo	The measurement is lower than 93.2 °F (34 °C)	Take the measurement again. Follow the steps in the "Take a measurement" section.
Hi	The measurement is higher than 109.4 °F (43 °C)	Take the measurement again. Follow the steps in the "Take a measurement" section.
Flashing battery symbol on the display	The battery is low on power	Replace the battery with two AAA (LR03) alkaline batteries.
Blank display	The thermometer does not have power	Make sure the battery has been loaded properly.
		Contact your local Welch Allyn service center or representative if the thermometer still does not function.

Maintenance

Replace the batteries

The thermometer comes with two AAA (LR03) batteries. Replace with two new AAA (LR03) batteries when the flashing battery symbol appears on the display

- 1. Use a Phillips screwdriver to loosen the battery cover screw.
- 2. Slide open the battery cover and remove the batteries.
- 3. Replace the batteries. Make sure to align the batteries as indicated inside the battery compartment.
- 4. Replace the battery cover and tighten the battery cover screw.

Remove the batteries before storing the thermometer for an extended period of time.

Clean and disinfect the thermometer

The thermometer can be cleaned and an intermediate-level of disinfection can be achieved using the following method.



CAUTION Never submerge the thermometer in water or any other liquid



CAUTION Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids.



CAUTION Never insert a sharp object into the scanner area or any other open surface on the thermometer.



CAUTION Do not use unapproved cleaning or disinfection agents. Use of these agents may cause damage to components.



CAUTION Do not use chemicals other than isopropyl or ethyl alcohol on the lens.

Cleaning the sensor window

Slightly moisten a cotton swab or cloth with isopropyl or ethyl alcohol and gently wipe the surface of the lens using a side-to-side (not circular) motion. Avoid touching the lens except when cleaning is required.

Cleaning the thermometer

Use a pre-moistened wipe or soft cloth slightly moistened with an approved cleaner to gently clean the thermometer.

Disinfecting the thermometer

Use a pre-moistened wipe or soft cloth slightly moistened with an approved disinfectant to disinfect the thermometer. Follow the manufacturers recommendations.



NOTE After cleaning or disinfecting, wait at least 10 minutes before taking another measurement.

Approved cleaning agents

Use only the following approved cleaning agents on the thermometer:

CaviWipes Super HDQ® L10

Sani-Cloth® Plus Cleancide

Super Sani-Cloth® Clorox HealthCare Bleach Germicidal Cleaner

Sani-Cloth® Bleach Virex II (256)

Oxiver Tb Tuffie5 Cleaning Wipes

Clinell® Universal Wipes 70% IPA

Accel INTERVention 10% bleach (.5% - 1% Sodium Hypochlorite)

Accel TB Desko

Additional cleaning agents may be periodically evaluated for compatibility. If your cleaning agent is not listed, contact Welch Allyn to determine if additional cleaning agents are approved for use.

Welch Allyn has validated these instructions as being capable of preparing the thermometer for reuse. You must ensure that cleaning and disinfection as actually performed by your personnel, with your equipment and materials, achieves the desired result. This may require validation and routine monitoring of your actual process.

Calibration testing

The thermometer is calibrated at the time of manufacture. If the thermometer is operating according to these instructions, periodic readjustment is not required.

These recommendations do not supersede any legal requirements. You must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device. These controls are required by the scope of relevant laws, directives or ordinances where the device is used.

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Disposal

Thermometer

The thermometer contains no hazardous materials. Discard without environmental risk. Remove the batteries before disposal.

Battery

Dispose of empty batteries in accordance with national or local regulations.

Specifications

Type Touch-free infrared thermometer

Model no. NT18, REF 901094, #105801

Displayed temperature range 93.2 to 109.4 °F (34 to 43 °C)

Display resolution 0.1 °F (0.1 °C)

Laboratory accuracy ± 0.4 °F (± 0.2 °C) for the range 93.2 to 109.4 °F (34 to 43

°C)

Clinical accuracy ± 0.5 °F (± 0.3 °C) for the range 93.2 to 109.4 °F (34 to 43

°C)

Display Liquid crystal display, four digits plus special icons

Operating temperature 60.8 to 104 °F (16 to 40 °C)

Operating humidity Up to 85% non condensing

Storage temperature -13 to 131 °F (-25 to 55 °C)

Storage humidity Up to 85% non condensing

Automatic power off Approximately 10 seconds after last measurement has

been taken

Battery $2 \times 1.5 \text{V AAA (LR03)}$

Battery life 3,300 measurements

Weight 100.5g (with battery), 78.0g (without battery)

Dimensions 159.3 x 41.3 x 55.8 mm

Software version NT18 V001

Standards

ASTM 1965-98 EN 12470-5:2003

MDD (93/42/EEC) Annex II ISO STD 80601-2-56

Guidance and manufacturer's declaration

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC EN 60601-1-2:2014.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document, the CareTemp[™] Touch Free Thermometer Directions for use
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the central station in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.

Emissions and immunity information

Electromagnetic emissions

The Welch Allyn CareTemp™ Touch Free Thermometer is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn CareTemp™ Touch Free Thermometer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Welch Allyn CareTemp™ Touch Free Thermometer 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 CareTemp™ Touch Free Thermometer is suitable for use in all establishments including domestic and those

Electromagnetic emissions			
Harmonic emissions Not applicable	directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		
IEC 61000-3-2			
Voltage fluctuations/ Not applicable flicker emissions			
IEC 61000-3-3			

Electromagnetic immunity

The Welch Allyn CareTemp™ Touch Free Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn CareTemp™ Touch Free Thermometer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±8 kV contact ±8 kV contact ±15 kV air ±15 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity
IEC 61000-4-2			should be at least 30%.
Electrical fast transient/burst	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital
IEC 61000-4-4	±1 kV for input/ output lines		environment.
Surge IFC 61000-4-5	±1 kV differential	Not applicable	Mains power quality should be that of a typical commercial or hospital
120 01000 1 3	±2 kV common mode		environment.
Voltage dips, short interruptions and voltage variations on	$<5\% U_T (>95\% dip in U_T) for 0.5 cycle$	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
power supply input lines	40 % U _T (60 % dip in U _T) for 5 cycles		
IEC 61000-4-11	70 % U_T (30 % dip in U_T) for 25 cycles		
	$<5 \% U_T (>95 \% dip in U_T) for 5 s$		
Power frequency (50/60 Hz) magnetic	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical
field IEC 61000-4-8	50Hz/60Hz	50Hz/60Hz	location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity

The Welch Allyn CareTemp™ Touch Free Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn CareTemp™ Touch Free Thermometer should assure that it is used in such an environment.

Immunity test	IEC 60601 test leve	l Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Connex Central Station, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distances:
			d = 1.2 \sqrt{P}
			$d=1.2\sqrt{P}$ $d=2\sqrt{P}$
Conducted RF	150KHz to 80MHz :	Not applicable	
IEC 61000-4-6	3Vrms		
	6Vrms (in ISM and amateur radio bands)		
	80% Am at 1kHz		
Radiated RF	10V/m	10V/m	d = 1.2 \sqrt{P} 80 MHz to 800 MHz
IEC 61000-4-3			ν - γΙ



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:



Note 1: 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.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically

Electromagnetic immunity

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 CareTemp™ Touch Free Thermometer is used exceeds the applicable RF compliance level above, the Welch Allyn CareTemp™ Touch Free Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Connex Central Station.

^b Over 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 CareTemp™ Touch Free Thermometer

The Welch Allyn CareTemp™ Touch Free Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Welch Allyn CareTemp™ Touch Free Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn CareTemp™ Touch Free Thermometer 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		80 MHz to 800 MHz	800 MHz to 2.7 GHz	
	d = 1.2 \sqrt{P}	$d=2\sqrt{P}$	d = 1.2 \sqrt{P}	$d=2.3\sqrt{P}$	
0.01	0.12	0.2	0.12	0.23	
0.1	0.38	0.632	0.38	0.74	
1	1.20	2	1.20	2.30	
10	3.8	6.32	3.8	7.3	
100	12	20	12	23	

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

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

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

Test specifications for enclosure port immunity to RF wireless communications equipment						
Test frequency (MHz)	Band ^a MHz	Service ^a	Modulation ^b	Maximum power (W)	Distance (m)	Immunity test level (V/ m)
385	380 - 390	TETRA 400	Pulse modulation ^b	1.8	0.3	27

			18 Hz			
450	430 - 470	GMRS 460, FRS 460	FM ^c ±5 kHz deviation	2	0.3	28
			1 kHz sine			
710	704 - 787	LTE band 13, 17	Pulse modulation ^b	0.2	0.3	9
745			217 Hz			
780						
810	800 - 960	GSM 800/900, TETRA 800,	Pulse modulation ^b	2	0.3	28
370		iDEN 820, CDMA 850,	18 Hz			
930		LTE Band 5				
1720	1700 - 1990	GSM 1800; CDMA 1900;	Pulse modulation ^b	2	0.3	28
1845		GSM 1900; DECT; LTE	217 Hz			
1970		Band 1, 3, 4, 25; UMTS				
2450	2400 - 2570	Bluetooth, WLAN, 802.11	Pulse modulation ^b	2	0.3	28
		b/g/n, RFID 2450,	217 Hz			
		LTE Band 7				
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation ^b	0.2	0.3	9
5500	<u>-</u>		217 Hz			
5785						

^a For some services, only the uplink frequencies are included.

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$\mathsf{E} = \frac{6}{d} \sqrt{P}$$

^b The carrier shall be modulated using a 50 percent duty cycle square wave signal.

^c As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Test specifications for enclosure port immunity to RF wireless communications equipment

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Warranty

Welch Allyn warrants the product to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents.

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 damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

Shipping cost to return a device to a Welch Allyn Service center is not included.

A service notification number must be obtained from Welch Allyn prior to returning any products or accessories to Welch Allyn's designated service centers for repair. To obtain a service notification number, contact Welch Allyn Technical Support.

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