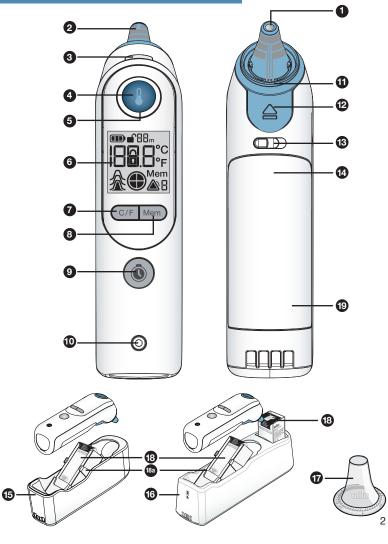


AL-82955 & AL-82956 **ThermoScan®** Ear thermometer Directions for use Œ C/F Mem •

AL-82955 & AL-82956

AL-82955, AL-82956



2. Package components

AL-82955 or AL-82956 thermometer

Cradle

Probe covers (1 or 2 probe cover boxes, depending on model)

CD containing Directions for use, Quick reference guide, Service Tool software and Service Tool installation guide.

2 (AA) Duracell® alkaline batteries

3. Product description (See 1. PRO 6000)

Probe lens window Probe cover detect switch 2 Probe Probe cover ejector 3 ExacTemp light Battery door latch 4 Measure button Battery door 6 Measure light Small cradle—one storage box 6 Display 16 Large cradle—two storage boxes C/F button Probe cover 8 Memory button Probe cover box 18a Probe cover box carrier 9 Timer button GTIN code 10 Tether mount (Tether sold separately)

4. Screen elements

Battery

Full battery - indicates battery is between 100% and 70% of usable battery capacity



Partial battery - indicates battery is between 70% and 30% of usable battery capacity



Low battery - indicates battery is between 30% and 10% of usable battery capacity

Critically low battery - battery is between 10% and 1% of usable battery capacity. When final segment flashes, batteries have low power. The thermometer will take a proper measurement but batteries must be replaced soon. If rechargeable batteries are in use, batteries should be recharged.

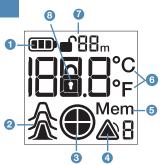
Empty battery - battery has 1% or less of usable battery capacity. When battery outline flashes, the thermometer will not operate. Replace the batteries. If rechargeable batteries are in use. batteries should be recharged. See 14.7 Maintenance and service, Replacing the batteries

Probe cover icon

The icon animates in an upward motion to remove probe cover. The icon animates in a downward motion to apply a probe cover.

8 Timer icon

The PBO 6000 includes a 60 second timer that features an audible notification and visual indicator at 0, 15, 30, 45, and 60 seconds. The first guadrant begins flashing when timer starts and becomes solid at 15 seconds. This repeats for each 15 second interval. The timer turns off automatically 5 seconds after 60 seconds is completed. See 10.3 Controls. Manual timer



Alert icon

Icon that appears with error message. See 12, Errors and notifications

6 Memory indicator

Indicates the reading shown on the display is the reading in memory. See 10.1 Controls, Memory

6 C/F scale

Indicates default temperature scale. Either °C or °F will display, depending on setting. See 10.2 Controls, C/F Celsius/Fahrenheit

Security unlock icon and countdown time

(Requires charging station or compatible Vital Signs device, sold separately.) If the security function is enabled, it requires the thermometer be returned to the charging station within a pre-selected time interval. Countdown time indicates the amount of time remaining until the thermometer will be locked if not returned to the charging station. See 11.2 Settings, Advanced functions

8 Security lock icon

(Requires charging station or compatible Vital Signs device, sold separately.) Indicates the thermometer is locked. Return the thermometer to the charging station to reset the countdown and resume normal operation. See 11.2 Settings, Advanced functions

5

5. About the AL-82955 & AL-82956

This thermometer is a clinical grade ear thermometer indicated for the intermittent measurement of human body temperature in patients of all ages in a professional use environment.

Please read all instructions carefully and thoroughly before using this product.

5.1 How does it work?

The ThermoScan technology reads the infrared energy emitted by the tympanic membrane and surrounding tissues to determine the patient's temperature. To help ensure accurate temperature measurements, the sensor itself is warmed to a temperature close to that of the human body. When the thermometer is placed in the ear, it continuously monitors the infrared energy until a temperature equilibrium has been reached and an accurate measurement can be taken. The thermometer displays an actual measured ear temperature or clinically accurate, oral equivalent temperature that has been validated in clinical studies by comparing IR measurements with the oral readings from afebrile and febrile patients of various ages. Unadjusted operating mode ear temperature readings are available via unadjusted mode, which can be accessed using the Service Tool.

5.2 PerfecTemp[™] technology

Speed and ease of access are two key advantages of ear thermometry. Concerns regarding accuracy and reliability have hindered adoption of this technology. In clinical studies, the precision of ear temperature measurement has been shown to be influenced by ear canal anatomy and variability in user technique. Proper probe placement can also be a challenge, particularly with young patients that move around during measurement. Shallow probe placement, coupled with anatomical variabilities such as ear canals with a small circumference and poor visibility of the tympanic membrane, can result in readings that are low compared to core temperature because the thermometer could be focused on the cooler outer ear canal.

The PRO 6000 thermometer incorporates a new proprietary technology, PerfecTemp™ technology, that overcomes the challenges presented by ear canal anatomy and variations in technique among clinicians. The thermometer collects information about the direction and depth of ear probe placement as it is placed into the ear canal and automatically incorporates this information into the temperature calculation. Incorporating information related to patient specific anatomy and exact ear probe placement in the ear canal increases the accuracy of the measurement as compared to core temperature, especially when probe positioning is not ideal.

5.3 ExacTemp[™] technology

The thermometer also features ExacTemp™ technology which supports temperature measurement reliability by detecting the stability of the probe placement during the measurement. The ExacTemp light flashes during the measuring process and remains illuminated when the measurement is complete, indicating consistent placement of the probe during the measurement process. Consistent probe placement helps support accurate temperature measurement.



Table 1: Ear canal temperature gradient



5.4 Why measure in the ear?

Clinical studies have shown that the ear is an excellent site for temperature measurement because temperatures taken in the ear reflect the body's core temperature'. Body temperature is regulated by the hypothalamus², which shares the same blood supply as the tympanic membrane³. Changes in core body temperature are usually seen sooner at the tympanic membrane than at other sites, such as the rectum, mouth or under the arm. Advantages of taking temperatures at the ear versus traditional sites:

 Axillary temperature measurements reflect skin temperature which may not reliably indicate the internal body temperature.



- Rectal temperatures often lag significantly behind internal body temperature changes, especially
 at times of rapidly changing temperatures. Also, there is a risk of cross contamination.
- Oral temperatures are often influenced by eating, drinking, thermometer placement, breathing through the mouth, or the inability of the person to close their mouth completely.

1. GUYTON A C, TEXTBOOK OF MEDICAL PHYSIOLOGY, W.B. SAUNDERS, PHILADELPHIA, 1996, P 919

GUYTON A C, TEXTBOOK OF MEDICAL PHYSIOLOGY, W.B. SAUNDERS, PHILADELPHIA, 1996, P 754-5

3. NETTER H F, ATLAS OF HUMAN ANATOMY, NOVARTIS MEDICAL EDUCATION, EAST HANOVER, NJ, 1997, PP 63, 95.

5.5 Body temperature



Normal body temperature is a range. The following table shows that this normal range also varies by site. Therefore, measurements from different sites, even if taken at the same time, should not be directly compared.

Normal ranges by site ¹ :			
Axillary ^{1,2} :	95.6 - 99.4°F	35.3 - 37.4°C	
Oral ^{1, 2} :	95.7 - 99.9 °F	35.4 - 37.7 °C	
Rectal ^{1, 2} :	96.6 - 100.8 °F	35.9 - 38.2 °C	
ThermoScan ^{1, 2} :	95.7 - 99.9 °F	35.4 - 37.7 °C	

A person's normal temperature range tends to decrease with age. The following table shows normal ThermoScan ranges by age.

Normal Ther	moScan range	s by age ^{1, 2} :
< 3 months	96.4 - 99.4 °F	35.8 - 37.4 °C
3 - 36 months	95.7 - 99.6 °F	35.4 - 37.6 °C
> 36 months	95.7 - 99.9 °F	35.4 - 37.7 °C

The range of normal varies from person to person and can be influenced by many factors such as time of day, level of activity, medications and gender.

- Sund-Levander M, Forsberg C, Wahren LK. Normal oral, rectal, tympanic and axillary body temperature in adult men and women: a systematic literature review. Scand J Caring Sci 2002 June;16(2):122-8.
- 2. Herzog L, Phillips SG. Addressing concerns about fever. Clin Pediatr (Phila) 2011 May;50(5):383-90.

6. Contraindications

Clinical studies have shown the thermometer can obtain accurate temperature measurements on full term newborn, pediatric and adult patients. However, there are special situations when an ear thermometer should not be used. These include, but may not be limited to the following situations:

- Do not use an ear thermometer if there is blood or drainage in the external ear canal.
- An ear thermometer should not be used on a patient who exhibits symptoms of an acute or chronic inflammatory condition of the external ear canal.
- Common situations like the presence of moderate amounts of cerumen (ear wax) in the ear canal, otitis
 media and tympanostomy tubes do not significantly impact temperature readings. However, complete ear
 canal occlusion due to cerumen (ear wax) can result in lower temperature readings.
- Use the untreated ear if prescription ear drops or other ear medications have been placed in the ear canal.
- Patients who have deformities of the face and/or ear may not be able to have a temperature taken with an
 ear thermometer.
- This thermometer is not intended for pre-term babies or small-for-gestational age babies.

6.1 What affects accuracy

Always use a new disposable probe cover for each measurement to maintain accuracy and hygiene. The right ear measurement may differ from the measurement taken in the left ear. Therefore, always take the temperature in the same ear. The ear must be free from obstructions or excess earwax build-up to take an accurate reading.

External factors may influence ear temperatures, including:

Factor	Affected	Not affected
Used probe cover	\checkmark	
Ambient temperature		\checkmark
Wet / dirty / damaged lens	\checkmark	
Hearing aid	\checkmark	
Lying on pillow	\checkmark	
Moderate cerumen (ear wax)		\checkmark
Otitis media (ear infections)		\checkmark
Tympanostomy tubes		\checkmark

In the event of lying on a pillow, ear plugs or hearing aid, remove the individual from the situation and wait 30 minutes prior to taking a temperature.



7. Warnings and precautions

This thermometer is for professional use only.

This thermometer must only be used with genuine ThermoScan probe covers.

Do not use any cleaning agent other than isopropyl or ethyl alcohol for cleaning the probe lens window and probe as specified in the cleaning section of this manual.

Do not use any cleaning agent other than the approved list of cleaners for cleaning the body of the thermometer.

To avoid inaccurate measurements, always attach a new, clean probe cover for each temperature measurement.

The probe lens window must be kept clean, dry and undamaged at all times to ensure accurate measurements. To protect the probe lens window, always keep the thermometer in the storage cradle while transporting or when not in use.

This thermometer is not intended for pre-term babies or small-for-gestational age babies.

Do not modify this equipment without authorization of manufacturer.

Never use the thermometer for purposes other than those it has been intended for. Please follow the general safety precautions.

Do not expose the thermometer to temperature extremes (below $-4^{\circ}F / - 25^{\circ}C$ or over 122°F / 55°C) nor excessive humidity (> 95 % RH).

This thermometer complies with current required standards for electromagnetic interference and should not present a problem to other equipment nor is it effected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

8. Setup

8.1 Battery installation

Your thermometer ships with two (AA) alkaline batteries. See 14.7 Maintenance and service, Replacing the batteries.

The Charging station (sold separately) ships with one rechargeable battery pack.

8.2 Mounting instructions (Large cradle only)

Mounting hardware not included.

The large cradle (2 box storage) can be mounted as an easily removable wall hanger or a permanent wall mount. All mounting must be done into a wall stud. To mount the cradle the following items are needed:

- 2 #8 wood or sheet metal, pan head screws, 3.2 cm (1.25") long
- · Ruler (or tape measure could be substituted)
- · Screwdriver to match drive of screws
- Remove probe cover box carrier from the cradle by rotating the probe cover box carrier forward.



2 Mount to wall:

• Removable wall hanger: Locate the stud on the wall. Mount the 1st screw in position 1 and the 2nd screw in position 2a.

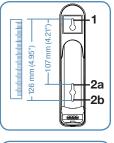
· Permanent wall mounting:

Locate the stud on the wall. Mount the 1st screw in position 1 and the 2nd screw in position 2b. Tighten screws.

Note: Permanent mounting is not recommended if using the charging station to access the security function, other advanced functions or charge the rechargeable battery.

8 Place probe cover box carrier back in cradle by lining up the brackets and pushing down.

Note: For a mounting template please reference the thermometer CD.





8.3 Tether installation

A kit to tether the thermometer to the cradle is available separately. Installation instructions are provided with the tethering kit.

9. Using the AL-82955 & AL-82956

Temperature measurement

Remove thermometer from cradle by gripping thermometer at base and pivoting up.

Thermometer will turn on automatically. Probe cover icon 🎊 will flash on display indicating a new probe cover is needed.





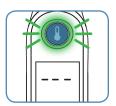
Attach new probe cover by pushing probe tip straight into box, then pulling thermometer out.







Wait for the ready indication. Ring around MEASURE button turns green, thermometer will beep once and three lines on display indicate thermometer is ready.



Place probe snugly

in ear canal and direct toward opposite temple. Keep thermometer probe steady in the ear canal. Correct probe placement is essential for accurate measurements.





5 Press and release MEASURE button.

The thermometer will beep once, running dashes will appear on the display then the green ExacTemp light will flash, indicating consistent probe position.

Note: Always press the MEASURE 🖁 button before taking a measurement.

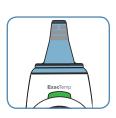
6 Temperature measurement. A long beep and steady green ExacTemp light will signal the end of the measuring process.

The temperature will show on the display.

If the thermometer is unstable or patient is moving during the measuring process, the device will beep, the green ExacTemp light will flash and POS (Position Error) will flash on the display. Be sure the device is stable and restrict patient movement for the next measurement. Change the probe cover to reset.

* See 12. Errors and notifications











Remove used probe cover by pressing Probe Cover Ejector button .

To achieve accurate measurements, use a new, clean probe cover for each measurement.

To take another measurement, place a new, clean probe cover on the thermometer. If no action is taken the thermometer will enter SLEEP mode after 10 seconds or upon return to the thermometer cradle or host device.



10.1 Memory

Press the MEMORY button to reveal the last completed temperature. The temperature will show with a MEM indicator until the MEMORY button is pushed again, a new probe cover is applied, or the thermometer enters sleep state. Memory can also be accessed from the thermometer sleep mode and will display for 5 seconds before returning to sleep.

10.2 C/F (Celsius/Fahrenheit)

Once the temperature scale has been set (See 11.1 Default temperature scale), the alternative scale can be quickly referenced at any time while a temperature is displayed.



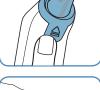
If the temperature scale is set to Celsius, press and release C/F button to view the temperature in Fahrenheit.

If the temperature scale is set to Fahrenheit, press and release C/F button to view the temperature in Celsius.



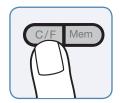
Press and release the C/F button again to revert back to default scale.

NOTE: If Temperature Conversion is disabled, refer to the Service Manual for more information.









10.3 Manual timer

The thermometer includes a 60 second timer that features an audible notification and visual indicator at 0, 15, 30, 45, and 60 seconds. The timer turns off automatically 5 seconds after 60 seconds is completed. The timer can be stopped at any time by pressing the Timer button or applying a probe cover. This feature can be used to time pulse, respirations, etc. To use this feature:



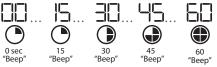
Press and hold timer button () for one second to activate timer. A beep is heard at initiation of the timer.

The display will show timer counting up in seconds.

The display will show an icon that has four 15 second quadrants.

The timer will beep at the completion of each 15 second interval to provide audible notification. Then the current segment will become solid and the next segment will flash.

At 60 seconds a long beep will sound, all quadrants will appear solid ending the timer function. The thermometer will exit the timer mode after an additional 5 seconds.







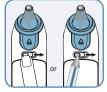
To stop the timer at any time, press the timer button.

11. Settings

11.1 Default temperature scale

To set the default temperature scale:

Open battery door by sliding spring latch to the right using your finger or a pointed object such as a pen. While holding the latch in the open position, grasp the battery door and remove it. Remove batteries and set aside. Once batteries are removed, C/F switch is accessible.





1

Slide switch to C or F using a pen or pointed object.

Place batteries back into thermometer. Snap the battery door back into place and ensure the latch returns to the original latched position. Celsius or Fahrenheit symbol will appear on the display.





11.2 Advanced functions

The following device settings must be completed using the Service Tool $\ensuremath{(See 11.3 Advanced function settings and 11.4 Service tools)}$

Item	Description	Settings	Default Setting
PerfecTemp™	Improves reading On/Off accuracy by detecting placement of probe in ear canal		On
Celsius only selection (Disables Fahrenheit)	Disables the C/F Celsius Only On/Of button and disables the Fahrenheit default selection on the device		Celsius Only Off
Security function time	Sets countdown time after removal from charging dock to lock	1 through 12 hours	Off
Timer icon	Displays an icon along with the timer counter	On/Off	On
Calibration check mode	Places thermometer in CAL mode to test calibration	Selection forces device into Test Mode in place of button press. Device remains in Test mode until unselected, button press sequence on device, or timeout occurs	Not applicable. A transient setting.
Unadjusted operating mode	Places thermometer in mode to detect raw ear temperature only	Allows user to set device to Unadjusted Operating Mode	Off

11.3 Advanced function settings

The charging station or compatible Vital Signs device can be used with the Service Tool to modify settings on the thermometer.

Follow the instructions to access advanced settings using the Service Tool.

Dock the thermometer in the Charging Station



2 The recommended action is to use the USB cable that connects to the wall adapter - unplug it from the wall adapter and plug it into your computer.



Se Log on prompt	8
Version 1.8.0.0	Service Tool
User Passw	ID ADMIN
	Remember me
Change password	
Welch/Allyn	© Welch Allyn, Inc. All rights reserved

3 Launch the Service Tool. If the log on prompt appears enter the User ID "ADMIN" (all caps) with no password

4 Click the Thermometer from the device list to highlight, then click the select button.

and click the log on button.





7

5 The Device tab opens.

6 Click the Configure tab to the right of the Device information tab.

Click the Change button in the current settings box. The configuration settings dialog box opens.





(8)	Select the setting you wish to enable or
<u> </u>	disable by clicking the check box next to
	the setting. A check mark indicates the
	setting will be enabled, an empty check box
	indicates the setting will be disabled. To
	select the Security function click the drop
	down menu and click the desired time or Off
	to disable. To restore the factory default
	settings click Restore Defaults. Once the
	desired settings are selected click the Save
	button to send the settings to the
	thermometer and close the box.



To close the box without changing the settings click the Cancel button.

11.4 Service tools

For more information, refer to the Service Tool installation guide. The service tool software and service tool installation guide are available on the CD provided with the thermometer.

11.5 Charging station for storage, charging and security function (optional)

A charging station is available. The charging station automatically recharges the thermometer when using the rechargeable battery which is included. Use of alkaline batteries in the thermometer while using the charging station is permitted but the alkaline batteries will not be charged.

The charging station has an electronic, individually adjustable security function which requires the thermometer to be returned to the station within an individually pre-selected time or the thermometer will be locked. The charging station serves as a convenient storage base which can also be wall mounted.



12. Errors and notifications

Error message	Situation	Solution
	No probe cover is attached (animates ON).	Attach new, clean probe cover.
	Used probe cover is attached (animates OFF).	Discard probe cover that is on and attach new, clean probe cover if taking another temperature measurement.
P05,	(POS = position error) The infrared monitor cannot find a temperature equilibrium and allows no measurement.	Change the probe cover to reset. Restrict patient movement and ensure that the positioning of the probe is correct and remains stable while taking new temperature.
Егг	Ambient temperature is not within the allowed operating range (50 - 104 °F or $10 - 40$ °C) or changing too rapidly.	Wait 20 sec. until thermometer turns off automatically, then turn on again. Ensure thermometer and patient are in an environment for 30 minutes where the temperature is between 50 °F and 104 °F or 10 °C and 40 °C.
H	Temperature taken is not within typical human temperature range. HI will be displayed when temperature is higher than 108°F	Change probe cover to reset. Then, make sure thermometer is properly inserted and take a new temperature.
LO	(42.2°C). LO will be displayed when temperature is lower than 68°F (20°C).	19

12. Errors and notifications

Error message	Situation	Solution
	System error (All icons display or display is blank)	Wait 20 seconds until the thermometer turns off automatically, then turn on again.
or B	If error persists,	reset the thermometer by removing the batteries and putting them back in.
	If error still persists,	batteries are dead. Insert new batteries.
	Battery is low, but thermometer will still operate correctly.	Insert new batteries.
	Battery is too low to allow temperature measurement.	Insert new batteries.

13. PerfecTemp[™] status

Error message	Situation	Solution
and .c (***	PerfecTemp technology is not functioning or disabled.	contact local Service Center or representative
	U is "Unadjusted Operating Mode". Mode used for raw temperature measurement. Requires service tool access to enable.	See 11.3 Advanced function settings and adjust settings via Service Tool or contact local Service Center or Representative

14. Maintenance and service

14.1 Cleaning and disinfecting the probe lens window and probe

Only use ThermoScan® disposable probe covers.

Do not use damaged, perforated, soiled or poor fitting probe covers. Do not reuse probe covers.

Dirty probe lens window = lower readings. Fingerprints, cerumen, dust and other soiling components reduce transparency of the tip and result in lower temperature measurements. If thermometer is placed in ear without a probe cover, clean immediately.

Do not damage probe lens window. Avoid touching probe lens window except when cleaning. If probe lens window is damaged return for service.

Do not modify, change or adjust probe lens window. These changes will affect calibration and accuracy of the thermometer. If probe lens window is damaged return for service.

Do not use cleaning solution other than isopropyl or ethyl alcohol to clean probe lens window and probe. Other cleaning agents can damage probe lens window and probe.

Cleaning and disinfecting procedure

The thermometer probe and probe lens window should be cleaned when there are fingerprints, cerumen, dust or other soiling components present, following the below directions:



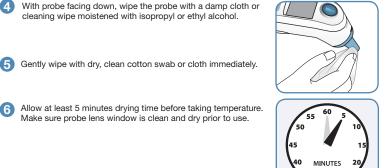
Remove probe cover and discard.





Moisten cotton swab or cloth slightly with isopropyl or ethyl alcohol. Do not saturate.

Gently wipe surface of probe lens window with cotton swab or cloth slightly moistened with isopropyl or ethyl alcohol only. Note: Use gentle pressure when cleaning the sensor to prevent damaging the unit by accidently changing the position of the sensor.



14.2 Cleaning and disinfecting the thermometer body and cradle

Do not submerge the thermometer. Excess liquid may cause damage to the thermometer.

Wipes should be moist, not saturated.

6

Do not use any chemical other than those listed in the Approved Cleaning Solution Table to clean the thermometer body and cradle. Other cleaning agents could cause damage to the thermometer.

When cleaning the probe lens window or probe ONLY use isopropyl or ethyl alcohol.

Do not use abrasives pads or cleaners.

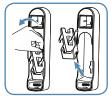
Approved cleaning solutions					
Family	Solution or Brand	Probe Lens Window	Probe	Thermometer Body & Cradle	Tether
Chlorine and Chlorine Compounds	10% Chlorine Bleach solution	No	No	Yes	Yes
Quaternary Ammonium Compounds	CaviWipes™ Clinell [®] Universal Wipes SaniCloth Metrex	No	No	Yes	Yes
Hydrogen Peroxide	Virox Oxivir	No	No	Yes	Yes
Alcohol	70% isopropyl or ethyl alcohol	Yes	Yes	Yes	Yes

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

As needed, clean the thermometer body and cradle following the below directions.

- For additional protection, we recommend placing a new probe cover on the thermometer probe to protect this area when cleaning the body of the thermometer.









2 Use a damp cloth or cleaning wipe with cleaning solution from the Approved Cleaning Solutions Table. To clean the body, ensure that the wipe is moist, not saturated. Wipe the body with

the display facing up.

8 Remove probe cover box carrier from the cradle by rotating the probe cover box carrier forward. See 14.5 Removing and installing probe cover box carrier

Wipe the cradle and probe cover carrier with a damp cloth or cleaning wipe with cleaning solution from the Approved Cleaning Solutions Table.



Allow at least 5 minutes drying time before taking temperature. Make sure probe, body and cradle are clean and dry prior to use.

14.3 Cleaning and disinfecting tether (sold separately)

1 To clean the tether, ensure that the wipe is moist, not saturated. Wipe the tether with a damp cloth or cleaning wipe with cleaning solution from the Approved Cleaning Solutions Table.

14.4 Installing new probe cover box



Keep out of reach of children.

strip. Discard perforated strips.

Remove empty probe cover box from probe cover box carrier by pulling up.

Open the new probe cover box. Pull down on the perforated









2

Insert new probe cover box into probe cover carrier by placing inside brackets and pushing down



14.5 Removing and installing probe cover box carrier



Remove thermometer from cradle by gripping thermometer at base and pivoting up.



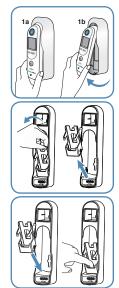
3

Remove probe cover box carrier from the cradle by rotating the probe cover box carrier forward.

Place probe cover box carrier back in cradle by lining up the brackets and pushing down.

14.6 Storage instructions

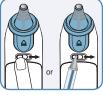
Store thermometer and probe covers in a dry location (the thermometer is not protected against ingress of water), free from dust and contamination and away from direct sunlight. The ambient temperature at the storage location should remain fairly constant and within the range of 50° F to 104° F (10° C to 40° C) to allow for immediate use.



14.7 Replacing the batteries

The thermometer is supplied with two 1.5 V batteries type AA (LR 6). For best performance, we recommend Duracell® alkaline batteries.

- Insert new batteries when the battery symbol begins to flash on the display (See 12. Errors and notifications).
- 2 Open battery door by sliding spring latch to the right using your finger or a pointed object such as a pen. While holding the latch in the open postion, grasp the battery door and remove it.





Remove the batteries and replace with new batteries, making sure the poles are in the right direction.

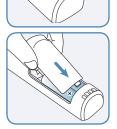
Snap battery door back into place and ensure the latch returns to original latch position.

This product contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it in the trash, but take it to appropriate local collection points according to national or local regulations.

14.8 Calibration testing

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required. However, We recommend checking calibration on an annual basis or whenever clinical accuracy of the thermometer is in question. Procedures for checking calibration are outlined in the Calibration Tester (REF 01802-110) directions for use manual.

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



15. Specifications

Displayed temperature range: Operating ambient temperature range: Display resolution Accuracy for displayed temperature range:

Clinical repeatability:

68–108°F (20–42.2°C) 50–104°F (10–40°C) 0.1°F or °C ±0.4°F ((±0.2°C) (35.0°C-42°C) (95°F - 107.6°F) ±0.5°F (±0.3°C) (outside this temperature range) <0.57°F (0.3°C)

Long term storage ranges

Storage temperature: Storage humidity: Shock: Warm up time: Measurement time: Automatic power down: Battery life: Battery type: Thermometer dimension: Thermometer weight: Pressure: -13-131°F (-25-55°C) 15%-95% non condensing Withstands drop of 3 feet (91.44 cm) Initial start-up time: 3-4 seconds 2-3 seconds 10 seconds 6 months/1000 measurements 2 x MN 1500 or 1.5 V AA (LR6) 6" x 1.7" x 1.3" (152 mm x 44 mm x 33 mm) 3.6 oz (100 g) without batteries 700-1060hPA (0.7-1.06 atm) The thermometer is specified to operate at 0.7-1.06 Atmospheric Pressure.



CAUTION: Do not use this device in the presence of electromagnetic or other interference outside the normal range specified in IEC 60601-1-2.





Standards and compliance

This device conforms to the following Safety and Performance standards:

This infrared thermometer meets requirements established in ASTM Standard E 1965-98 (for the thermometer system [thermometer with probe cover]). Full responsibility for the conformance of the product to the standard is assumed by Kaz USA, Inc., 250 Turnpike Road, Southborough, MA 01772, USA.

This product conforms to the provisions of the EC directive 93/42/EEC (Medical Device Directive).

A clinical summary is available upon request.

EN 60601-1:2006 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance EN 12470-5: 2003 Clinical thermometers – Part 5: Performance of infra-red ear thermometers (with maximum device)

Meets CB Scheme

EN 60601-1-2 :2007, IEC 60601-1-2:2007 General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic Compatibility–Requirement & Tests Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and test

IEC 62304 :2006 Medical device software- Software life cycle processes

IEC 62366 :2007 (IEC60601-1-6) Medical devices -Application of usability engineering to medical devices

EN980 :2008 Symbols for use in the labelling of medical devices

ISO14971 :2007 Medical devices -Application of risk management to medical devices

ISO 80601-2-56 :2009 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (includes US FDA Blue book memo G95-1-100 Title)

GBT 21417.1:2008

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC. For detailed description of EMC requirements please contact an authorized local Service Centre.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT

Internally powered ME equipment. Continuous operation. Not protected against ingress of water.



Symbol definitions:



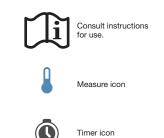
BF APPLIED PART



Caution



This product contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it in the trash, but take it to appropriate local collection points according to national or local regulations.



16. Warranty

For AL-82955 & AL-82956

The thermometer has a limited three year warranty and the cradle has a limited one year warranty. The instrument is warranted by ALCO Sales & Service Co. to be free from defects in material and workmanship under normal use and service for a period of three years from the date of delivery to the first professional user who purchases the instrument.

This warranty does not cover batteries, damage to the probe window, or damage to the instrument caused by misuse, negligence or accident and extends to only to the first purchaser of the product. Additionally this warranty becomes void if the thermometer is operated with anything other than genuine ThermoScan® Probe Covers.

Thermometer service or replacement will be carried out subject to the terms of this warranty. Loss or damage in return shipment shall be at purchaser's risk. ALCO reserves the right to replace a nonconforming product with the most comparable product currently available. This product has a five year minimum expected lifetime.

IN NO EVENT SHALL ALCO BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THE PURCHASE OR USE OF ANY PRODUCT. This warranty shall not apply to, and ALCO shall not be responsible for, any loss arising in connection with the purchase or use of any product which has been serviced by anyone other than an ALCO authorized service representative or altered in any way so as, in ALCO's judgment, to affect its stability or reliability, or which has been subject to misuse or negligence or accident, or which has the serial number or lot number altered, effaced or removed, or which has been used other than in accordance with the instructions furnished by ALCO. IN NO EVENT SHALL ALCO'S LIABILITY EXCEED THE ORIGINAL COST OF THE PRODUCT.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities on ALCO's part, and ALCO neither assumes nor authorizes any representatives or other person to assume for it any other liability in connection with the sale of its products.

TO THE EXTENT PERMITTED BY LAW, ALCO DISCLAIMS ALL STATUTORY AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Guidance and manufacturers declaration- electromagnetic Immunity			
The thermometer is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters,
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80Mhz	Not applicable (no electrical cabling)	as determined by an electromagnetic site survey, should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol: (()) Separation distance calculation provided below. If a known transmitter is present the specific distance can be calculated using the equations.
Electrical fast transient IEC 61000-4-4	±2kV power line ± 1kV I/O lines	Not applicable	Thermometer is solely battery powered
Surge IEC 61000-4-5	± 1kV differential ± 2kV common	Not applicable	
Power frequency Magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Voltage dips, short interrupts and voltage variations on power supply input lines IEC61000-4-11	> 95% dip 0.5 cycle 60% dip 5 cycles 70% dip 25 cycles 95% dip 5 sec.	Not applicable	Thermometer is solely battery powered

Guidance and manufacturer's declaration – electromagnetic emissions			
The thermometer is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.			
Emissions test Compliance Electromagnetic environment - Guid			
RF emissions CISPR 11	Group 1	Thermometer uses RF energy only for it's 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 BF	Complies	
Harmonic emissions IEC 61000-3-2	N/A		
Voltage fluctuations / flicker emissions	N/A	Thermometer is solely battery powered.	

Non-life support equipment separation distance calculation (3Vrms / 3V/m compliance)			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz in ISM bands <i>d</i> =[3.5/V ₁]√P	80 MHz to 800 MHz <i>d</i> =[3.5/E ₁]√P	800 MHz to 2.5 GHz =[7/E,]√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

Guidance and manufacturer's declaration - electromagnetic emissions





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