

Assessing the Use of Infrared Thermometers for Vaccine Temperature Determination

The use of infrared thermometers (IRTs) as an effective tool to measure the storage temperature of vaccines both for daily use and for on-site field assessment is explored. For this study, we tested four different IR thermometers from four different manufactures (ranging in price from \$50 to \$500). The repeatability, reliability and accuracy of the IRTs were tested with respect to the vaccine storage temperature requirements of ± 0.5 °C over the temperature range from 2 °C to 8 °C. Additionally, we used an ice melting point (0 °C) as a mechanism to validate the IRT accuracy and re-establish traceability.

Summary of results:

The use of an infrared thermometer (IRT) for accurately measuring vaccine storage temperature to within ± 0.5 °C of the true storage temperature is not feasible. Measurements at a fixed temperature (5 °C) showed that the IRTs consistently read too high in temperature regardless of the measurement condition (e.g., storage system and target type). Use of such high readings would force a set point temperature that is colder than that of the 2 °C to 8 °C temperature storage range. In one case, the IRT results yielded a set point change that would cause the stored vaccines to be frozen. Using a metrologically traceable ice melting point (0 °C) with an intrinsic realization uncertainty of ± 0.002 °C shows that an IR thermometer cannot reliably measure 0 °C to within the required accuracy of ± 0.5 °C.

Our measurement results show that the IRT repeatability, reliability and accuracy are inadequate for both in-house use and on-site field assessment of vaccine storage systems. Additionally, the use of a simple to realize ice melting point shows that an IRT calibration status is difficult to verify and that a recalibration is problematic.

Objective and Test Parameters:

Determine if an IRT can be used to accurately measure vaccine storage temperatures (2 °C to 8 °C) to within ± 0.5 °C

- Three (3) different vaccine storage systems operating at 5 °C
 - Pharmaceutical-grade
 - Single zone (no freezer)
 - Dual zone (with separate freezer)
- Six different measurement targets
 - Back center wall of storage system
 - Vaccine vial
 - Vaccine storage box
 - White paper cone target
 - Matte-black paper cone target
 - Glycol-filled bottle
- Reference temperature determined using a NIST calibrated Type K thermocouple in a glycol-filled bottle
- IRTs held at the plane of the open door
- Four different IRTs (ranging in price from \$50 to \$500) tested

IRT results of measuring the temperature of vaccine storage systems operating at 5 °C

Table 1. IR thermometer measurement results using different targets inside of a dual-zone refrigerator held at 5 °C.

Dual 0° tilt	Thermometer				
	Target	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
	Back ctr wall	6.4	2.9	3.9	8.8
	Vaccine vial	6.9	6.1	7.6	10.5
	Vaccine box	8.3	9.4	8.3	9.8
	Glycol bottle	6.0	6.6	8.3	11.3
	Cone-white	15.1	15.8	13.2	12.3
	Cone- black	11.3	10.0	10.9	12.4

Dual 45° tilt	Thermometer				
	Target	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
	Back ctr wall	6.8	2.7	5.8	11.8
	Vaccine vial	5.9	6.5	7.8	8.8
	Vaccine box	10.3	9.3	8.8	10.7
	Glycol bottle	6.5	6.1	9.7	10.6
	Cone-white	13.1	11.6	12.3	14.6
	Cone- black	12.3	12.9	11.1	12.8

For the dual-zone refrigerator, all four (4) IRTs failed to meet the accuracy requirements of ± 0.5 °C at 5 °C (100% failed). As seen in figure 1, regardless of the target type and the orientation of the IRT the measurement results were too high by an average of 4.4 °C with a standard deviation of 3.1 °C. The wide variability in the results is unacceptable. To meet a 95% confidence interval, only 5% of the measurements (2 out of 48) should fall outside of the acceptability range. If you used this average value to set the temperature of a vaccine storage system with respect to a 5 °C set point temperature, your vaccines would be stored at 0.6 °C – a temperature too cold and outside the acceptable 2 °C to 8 °C temperature range.

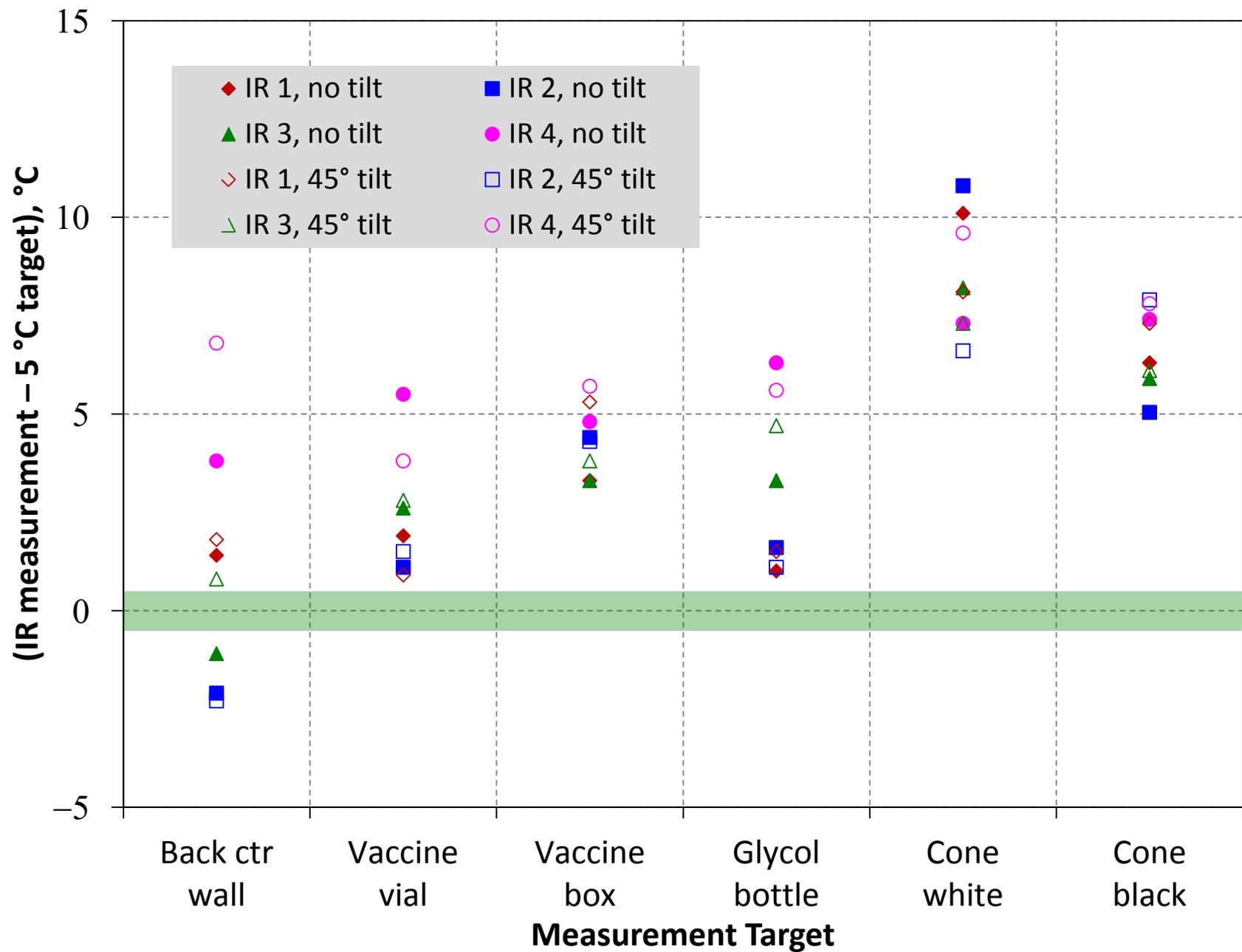


Figure 1. IR thermometers tested with targets in a dual-zone refrigerator at 5 °C. The green zone represents an acceptable measurement range of ± 0.5 °C around the 5 °C measurement temperature.

Table 2. IR thermometer measurement results using different targets inside of a freezerless refrigerator held at 5 °C.

Freezerless 0° tilt	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Back ctr wall	1.2	2.4	4.4	5.4
Vaccine vial	4.5	5.3	6.7	10.3
Vaccine box	8.4	10.3	7.5	8.4
Glycol bottle	4.9	6.1	8.8	8.1
Cone-white	14.2	15.9	13.9	15.9
Cone- black	12.5	10.1	12.3	10.2

Freezerless 45° tilt	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Back ctr wall	3.4	6.2	3.6	10.5
Vaccine vial	3.7	5.6	7.7	8.8
Vaccine box	9.7	10.7	8.8	9.8
Glycol bottle	4.2	5.4	9.3	9.2
Cone-white	16.2	14.8	11.4	12.9
Cone- black	8.8	9.1	12.0	9.2

For the freezerless refrigerator, all four (4) IRTs failed to consistently meet the accuracy requirements of ± 0.5 °C at 5 °C (90% failed). As seen in figure 2, regardless of the target type and the orientation of the IRT the measurement results were too high by an average of 3.7 °C with a standard deviation of 3.7 °C. The wide variability in the results is unacceptable. To meet a 95% confidence interval, only 5% of the measurements (2 out of 48) should fall outside of the acceptability range. If you used this average value to set the temperature of a vaccine storage system with respect to a 5 °C set point temperature, your vaccines would be stored at 1.3 °C – a temperature too cold and outside the acceptable 2 °C to 8 °C temperature range.

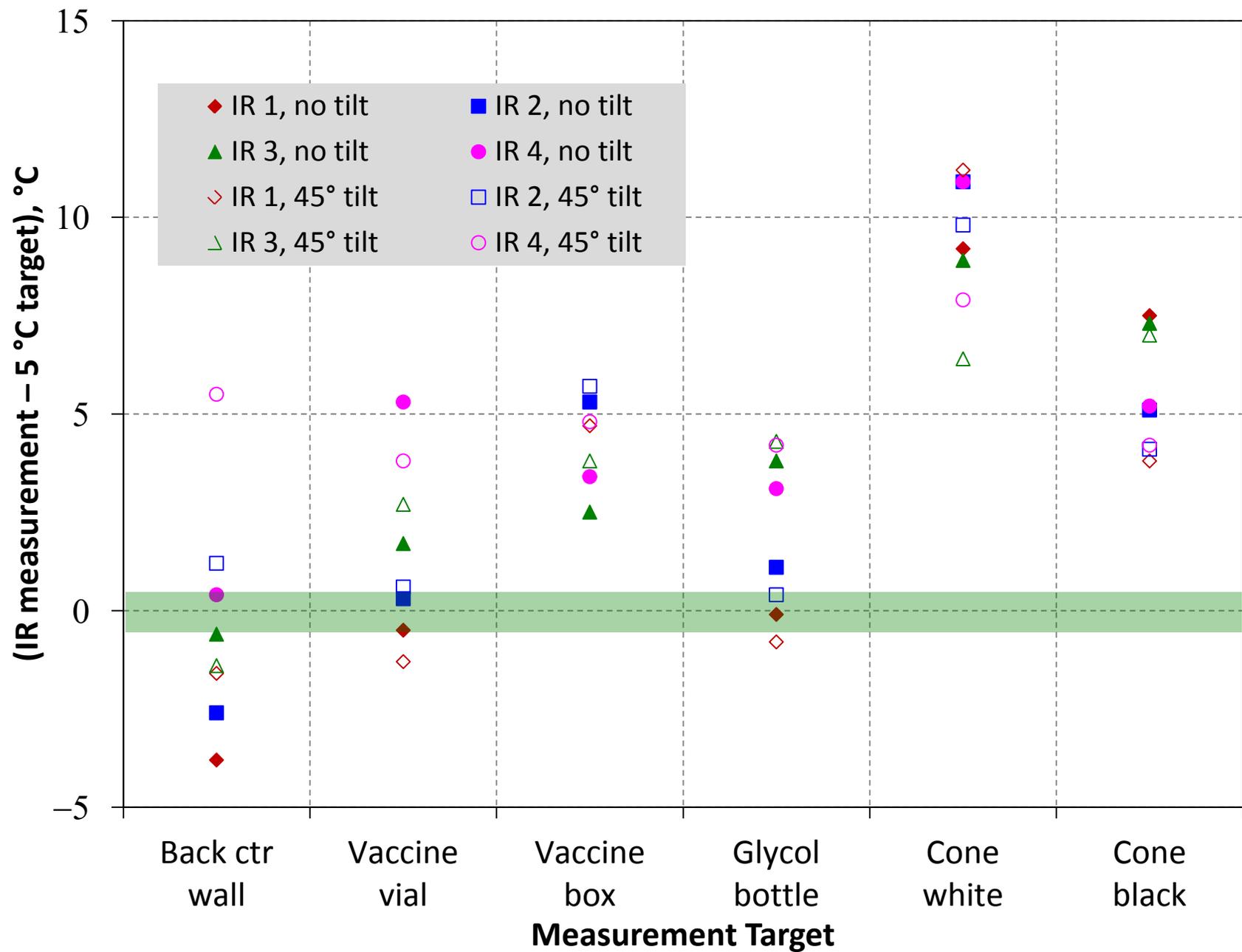


Figure 2. IR thermometers tested with targets in a freezerless refrigerator at 5 °C. The green zone represents an acceptable measurement range of ± 0.5 °C around the 5 °C measurement temperature.

Table 3. IR thermometer measurement results using different targets inside of a small pharmaceutical refrigerator held at 5 °C.

Small Pharmaceutical 0° tilt	Thermometer				
	Target	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
	Back ctr wall	5.1	8.9	13.3	8.9
	Vaccine vial	6.9	9.6	11.8	10.0
	Vaccine box	9.9	10.4	11.1	8.3
	Glycol bottle	6.1	8.5	10.9	7.4
	Cone-white	9.6	8.9	11.0	8.5
	Cone- black	8.8	9.1	12.0	9.2

Small Pharmaceutical 45° tilt	Thermometer				
	Target	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
	Back ctr wall	6.5	11.3	14.0	8.7
	Vaccine vial	5.8	9.3	13.5	7.9
	Vaccine box	9.2	10.5	12.3	9.2
	Glycol bottle	6.2	9.9	11.8	8.7
	Cone-white	9.0	9.7	13.3	10.6
	Cone- black	10.1	8.0	11.9	7.1

For the small pharmaceutical refrigerator, all four (4) IRTs failed to consistently meet the accuracy requirements of ± 0.5 °C at 5 °C (98% failed). As seen in figure 3, regardless of the target type and the orientation of the IRT the measurement results were too high by an average of 4.1 °C with a standard deviation of 2.1 °C. The wide variability in the results is unacceptable. To meet a 95% confidence interval, only 5% of the measurements (2 out of 48) should fall outside of the acceptability range. If you used this average value to set the temperature of a vaccine storage system with respect to a 5 °C set point temperature, your vaccines would be stored at 0.9 °C – a temperature too cold and outside the acceptable 2 °C to 8 °C temperature range.

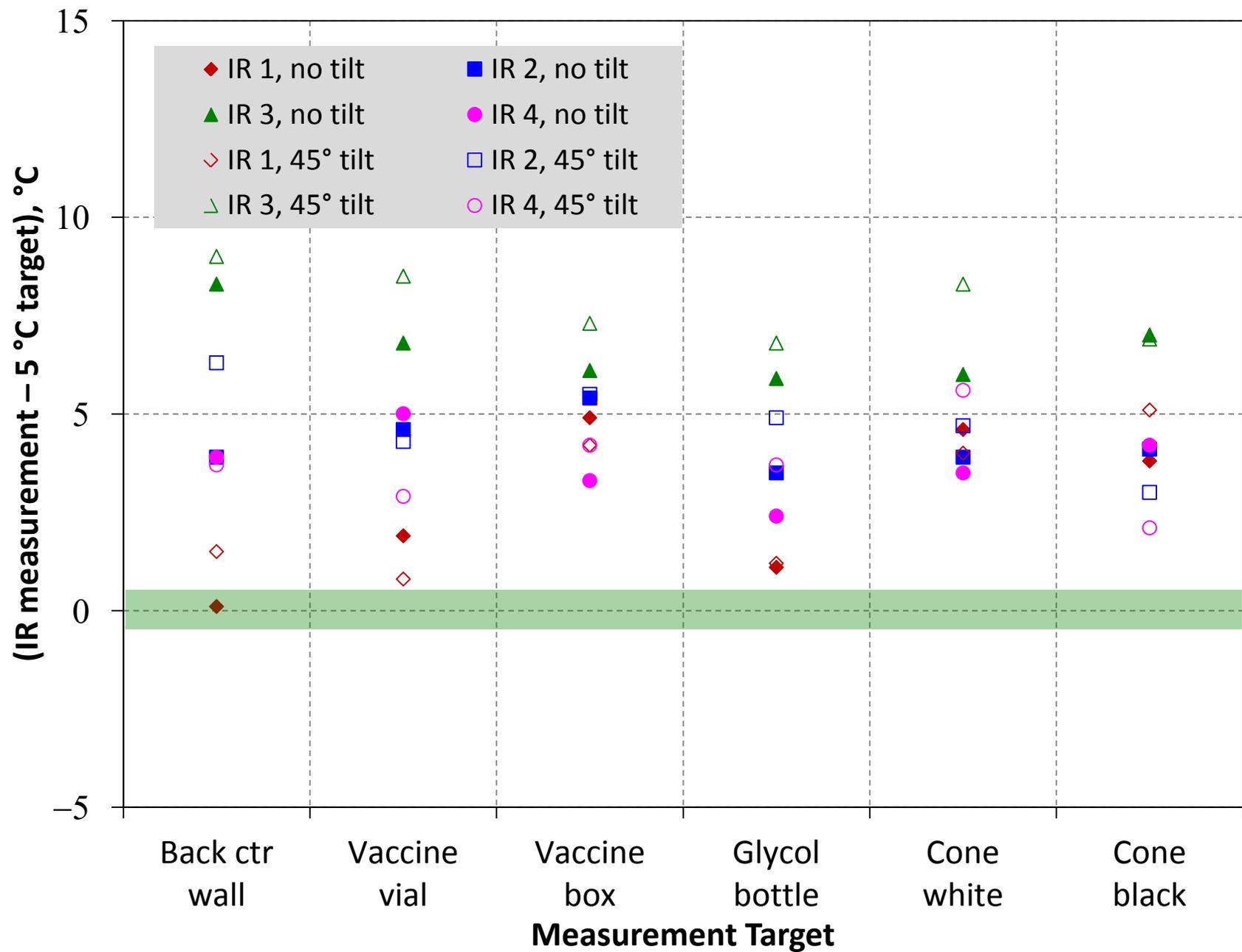


Figure 3. IR thermometers tested with targets in a small pharmaceutical refrigerator at 5 °C. The green zone represents an acceptable measurement range of ± 0.5 °C around the 5 °C measurement temperature.

Table 4. IR thermometer measurement results using different targets inside of a large pharmaceutical refrigerator held at 5 °C.

Large Pharmaceutical Open Door 0° tilt	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Back ctr wall	7.7	7.4	8.8	8.6
Vaccine vial	8.2	7.7	11.4	14.1
Vaccine box	11.3	10.2	11.8	12.8
Glycol bottle	7.5	7.3	13.3	14.4
Cone-white	15.8	16.3	16.8	14.8
Cone- black	14.2	12.8	10.9	11.9

Large Pharmaceutical Open Door 45° tilt	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Back ctr wall	8.9	8.0	8.5	7.5
Vaccine vial	7.5	6.9	9.6	9.3
Vaccine box	13.5	9.2	10.4	7.8
Glycol bottle	7.0	7.3	12.1	8.3
Cone-white	17.7	17.4	18.0	15.4
Cone- black	14.5	12.1	12.1	12.1

For the large pharmaceutical refrigerator, all four (4) IRTs failed to consistently meet the accuracy requirements of ± 0.5 °C at 5 °C (100% failed). As seen in figure 3, regardless of the target type and the orientation of the IRT the measurement results were too high by an average of 6.2 °C with a standard deviation of 3.3 °C. The wide variability in the results is unacceptable. To meet a 95% confidence interval, only 5% of the measurements (2 out of 48) should fall outside of the acceptability range. If you used this average value to set the temperature of a vaccine storage system with respect to a 5 °C set point temperature, your vaccines would be stored at -1.2 °C – a temperature too cold and significantly outside the acceptable 2 °C to 8 °C temperature range (e.g., below freezing).

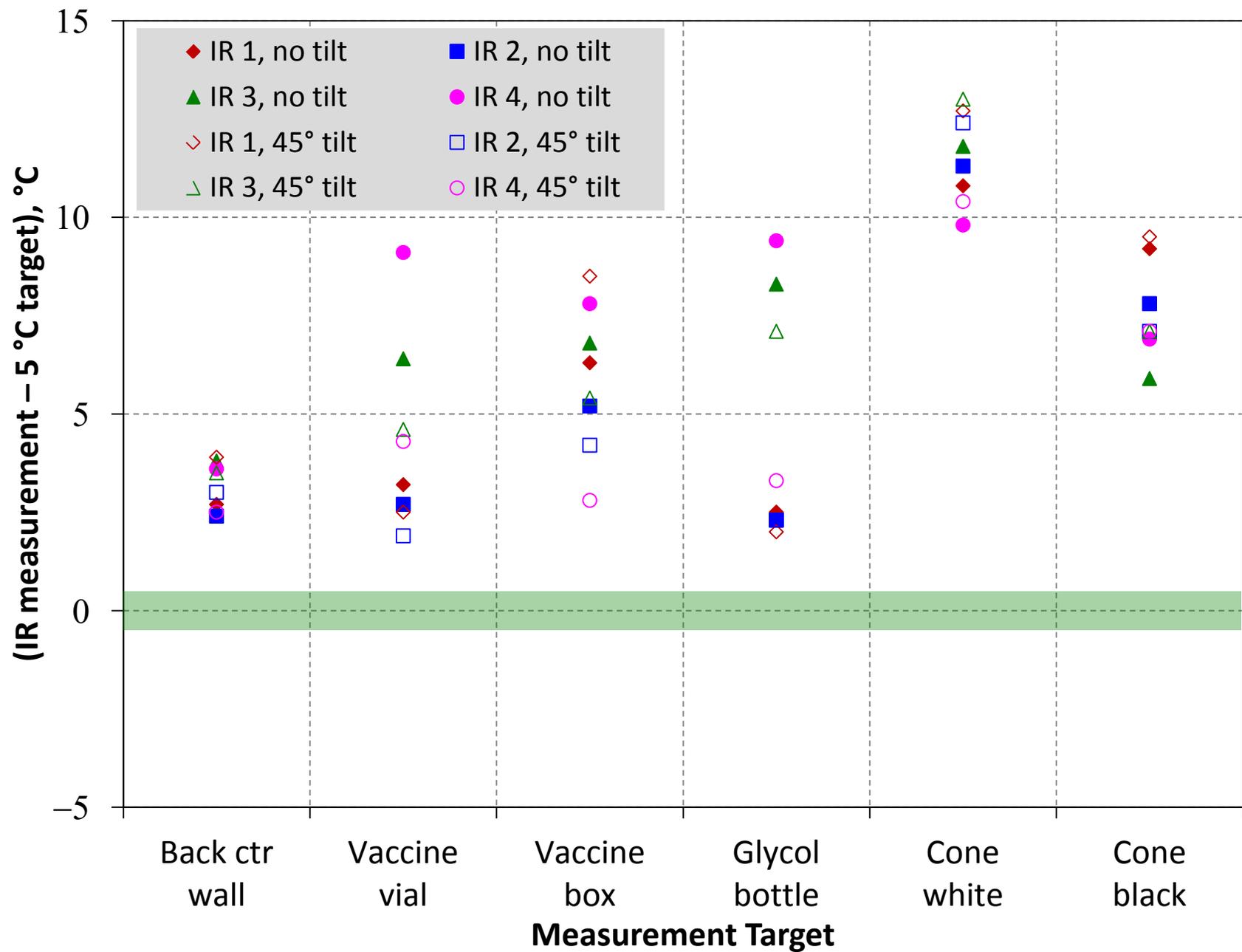


Figure 4. IR thermometers tested with targets in a large pharmaceutical refrigerator at 5 °C. The green zone represents an acceptable measurement range of ± 0.5 °C around the 5 °C measurement temperature.

Objective and Test Parameters:

Determine if an IRT calibration status can be accurately determined or recalibration performed to within $\pm 0.5\text{ }^{\circ}\text{C}$ at $0\text{ }^{\circ}\text{C}$ (Ice Melting Point)

- Five (5) different realization methods / measurement targets
 - Styrofoam cup – open top
 - Aseptic container / Beige tape target
 - Aseptic container / Matte Black painted tape target
 - Aluminum soda can / Beige tape target
 - Fluke IR calibration target
- Four different IR thermometers (ranging in price from \$50 to \$500) tested

Using an IRT calibration target to test IR thermometers at $0\text{ }^{\circ}\text{C}$ (Ice Melting Point).

Procedure:

- Fill styrofoam cup with distilled water and distilled water ice.
- Place IR target on top of Ice Point
- Allow 20 min for equilibration
- Use each IR thermometer to find temperature of target
 - 12 inches from target face

Using the IRT target equilibrated to the ice melting point ($0\text{ }^{\circ}\text{C}$), results show that two of the four IRTs do not meet the $\pm 0.5\text{ }^{\circ}\text{C}$ accuracy requirement. One IRT (IR 2) is minimally acceptable.

	Thermometer			
	IR 1, $^{\circ}\text{C}$	IR 2, $^{\circ}\text{C}$	IR 3, $^{\circ}\text{C}$	IR 4, $^{\circ}\text{C}$
Styrofoam cup IRT target	-0.3	0.5	13.5	6.4

Using an aseptic container as a calibration target to test IR thermometers at 0 °C (Ice Melting Point) – Beige masking tape target face

Procedure:

- Aseptic container with screw cap
 - e.g., Coconut Water flat sided container approximately 3" X 3" X 6"
- Wrap w/ one (1) layer of beige masking tape.
- Fill w/ tap water and Freeze
- Remove container from freezer
- Use each IR thermometer to measure the container temperature at
 - 0, 10, 20, 30, and 70 minutes elapsed time
 - 12 inches from target face – flat side face of container

Using an aseptic container with a beige-colored target equilibrated to the ice melting point (0 °C), results show that all four IRTs do not meet the ± 0.5 °C accuracy requirement. Measurements over elapsed time (10 min to 70 min) did not improve the results. All IRTs read too high in temperature.

	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Ascpitic container side - beige	2.1	2.8	17.9	14.4

Using an aseptic container as a calibration target to test IR thermometers at 0 °C (Ice Melting Point) – Matte black painted masking tape target face

Procedure:

- Aseptic container with screw cap
 - e.g., Coconut Water flat sided container approximately 3" X 3" X 6"
- Wrap w/ beige masking tape
 - Three (3) layers to give a more uniform surface
- Spray with matte black paint on three (3) sides
 - Let paint dry
- Fill w/ tap water and Freeze
- Remove container from freezer
- Use each IR thermometer to measure the container temperature at
 - 0, 10, 20, 30, and 70 minutes elapsed time
 - 12 inches from target face – matte black flat side face of the container

Using an aseptic container with a matte-black-colored target equilibrated to the ice melting point (0 °C), results show that all four IRTs do not meet the ± 0.5 °C accuracy requirement. Measurements over elapsed time (10 min to 70 min) do not improve the results. All IRTs read too high in temperature.

	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Aseptic container side - matte black	2.4	3.3	16.9	12.5

Using an aluminum soda can as a calibration target to test IR thermometers at 0 °C (Ice Melting Point) – Beige masking tape and water-ice mixture as target faces

Procedure:

- Remove top of can
- Wrap can in one (1) layer of beige masking tape
- Fill with ice and water
- Allow 20 min for equilibration
- Use each IR thermometer to find temperature of target
 - ½ inch from target faces (side of can, open top directly to the ice and water mixture)
 - 12 inches from target faces (side of can, open top directly to the ice and water mixture)

Using an aluminum soda can with a side beige-colored target equilibrated to the ice melting point (0 °C), results show that all four IRTs do not meet the ±0.5 °C accuracy requirement. Measurements over elapsed time (10 min to 70 min) do not improve the results. Moving from a 12 inch to a 0.5 inch target distance improved the results for 3 of the 4 IRTs, but not enough to meet the ±0.5 °C accuracy requirements. All IRTs read too high in temperature.

Using the same aluminum soda can with an open top target directly to the ice and water mixture [ice melting point (0 °C)], results show that all four IRTs do not consistently meet the ±0.5 °C accuracy requirement. Measurements over elapsed time (10 min to 70 min) do not improve the results.

	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Aluminum soda can side - beige 12 inches	1.3	3.5	18.3	15.3
Aluminum soda can side - beige 0.5 inches	1.3	0.9	2.3	3.3

	Thermometer			
	IR 1, °C	IR 2, °C	IR 3, °C	IR 4, °C
Aluminum soda can open top 12 inches	-0.6	0.2	18.6	15.0
Aluminum soda can open top 0.5 inches	-0.6	-2.3	-0.3	-0.1