United States
Consumer Product Safety Commission

November 14, 2024

Ms. Joan Lawrence, ASTM F15.22 Subcommittee Chair
Mr. Jos Huxley, ASTM F15.22 Task Group Chair
Ms. Carol Pollack-Nelson, F15.77 Subcommittee Chair
Mr. Alan Kaufman, F15.77 Subcommittee Chair
ASTM International
100 Barr Harbor Drive
West Conshohocken, PA 19428

Dear Ms. Lawrence, Mr. Huxley, Ms. Pollack-Nelson, and Mr. Kaufman:

On September 27, 2024, the U.S. Consumer Product Safety Commission (CPSC) staff[1] sent a letter to both ASTM F15.22 and F15.77 subcommittee chairs notifying them of an incident involving a child injured due to the interaction of ingested magnets. The letter noted that medical intervention was required to safely remove 17, 2.5 mm diameter spherical magnets. Staff acquired and tested the ingested magnets, calculated the flux indices, and found results below the current limit of 50 kG^2 mm^2.

The subcommittee chairs responded to CPSC staff's letter requesting 1) clarification on whether the incident magnets "adhered across intestinal tissue, or alternatively, formed a ring …that ended up stranded on an internal projection in the intestinal tract," and 2) updates on the ISO TC 181 Working Group 1 magnet strength and measurement round robin testing, which resulted in varied flux indices readings.

1.) To address the first request, CPSC staff reviewed the medical reports, specifically pictures taken during the colonoscopy, and concluded that the magnets did interact and formed a ring around an internal projection (a fold) in the child's large intestines (the cecum). Staff did not otherwise observe evidence of magnet interaction across the intestinal lining in this case.

2.) Regarding the update, CPSC staff recognizes that because each test lab received different sample magnets for measurement readings, we cannot determine "whether this variability is due to intrinsic variation in diameter and/or flux density of the magnets themselves," as the Committee chair asked, or whether it is related to differences in measurement

[1] The views in this letter are those of the staff and have not been reviewed or approved by, and may not reflect the views of, the Commission.

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

technique, or both.

Recently, CPSC staff provided several third-party accredited labs with a random sample of identical magnets to evaluate and calculate the flux indices by having each lab test identical magnets, the study eliminated the possibility of differences in the tested sample magnets causing variation in measured flux indices, indicating that the variation is due to the measurement technique. An incorrect or inconsistent measurement technique may lead to incorrect results and, most concerningly, results that are lower than what could be experienced by the victim.

As a result of this testing, CPSC staff has finalized and is enclosing (see enclosure 1) guidance for measuring small, rare-earth magnets. This guidance is consistent with the requirements specified in both ASTM F963-23 and 16 CFR part 1262. However, the guidance contains greater detail on how to locate the magnet poles, which CPSC believes is likely the main reason why varying results have been recorded by other labs. The method also provides more accuracy in sweeping the pole area(s) to determine the peak flux. CPSC staff assesses that the additional test equipment and more detailed test method outlined in the guidance will support labs in conducting this testing more precisely, reliably, and repeatably.

If you have any questions about the enclosed guidance, CPSC staff is happy to discuss.

Thank you for your continued work to revise and improve consumer product safety through ASTM F963 and F3458.

Sincerely,

BENJAMIN MORDECAI Digitally signed by BENJAMIN MORDECAI
Date: 2024.11.14 15:34:29 -05'00'

Benjamin Mordecai, Mechanical Engineer
Project Manager, ASTM F963
Directorate for Laboratory Sciences

STEPHEN HARSANYI Digitally signed by STEPHEN HARSANYI
Date: 2024.11.14 15:39:04 -05'00'

Stephen Harsanyi
Engineering Psychologist,
Directorate for Engineering Sciences

Cc: Molly Lynyak, ASTM F15 Staff Manager
Don Mays, ASTM F15 Chair
Jacqueline Campbell, CPSC Voluntary Standards Coordinator
Daniel Taxier, Children's Program Manager

Enclosure(s):

Enclosure 1

ASTM F963-23; Section 8.25 Proposal to Improve Magnet Flux Measurement Repeatability

1.0 Purpose

The purpose of this proposal is to provide more specificity in the test method to calculate the flux index of small, rare-earth magnets having various shapes using calibrated equipment and tools to reduce variability in test results due to the difficulties in handling small magnets and determining the location of the magnetic poles. This test method can be used for any sized spherical, rectangular, or cube magnets.

2.0 Tools and Equipment

a. Direct current (DC) field gaussmeter with a resolution of 5 gauss (G) or higher, capable of determining the field with an accuracy of 1.5% or better. The gaussmeter having an axial type probe with: an active area diameter of 0.76 +/- 0.13mm and a distance between the active area and probe tip of 0.38 +/- 0.13mm (Figure 1).
    i. F71 Multi-Axis Teslameter provided and calibrated by Lake Shore Cryotronics Inc.
    ii. FP-2X-250-ZS15 3-Axis Probe provided and calibrated by Lake Shore Cryotronics, Inc.

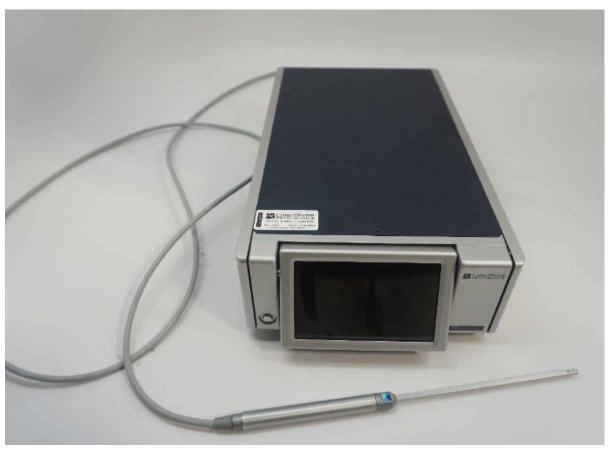

Figure 1: Teslameter and Probe

b. Test stand assembly (Figure 2) including:
    i. Vertical adjustable stand.
    ii. 40mm x 40mm Z-axis stage provided by Opto Sigma (Part# TADC-401SUU).
    iii. Clamp mount for probe.

iv. 65mm x 65mm XY-axis stage provided by Opto Sigma (part# TSD-652CUU).
v. Wooden block (2x4) mounted to the XY-axis stage using 4x brass or other non-ferrous screws.
vi. Double-sided tape placed on the wooden block.

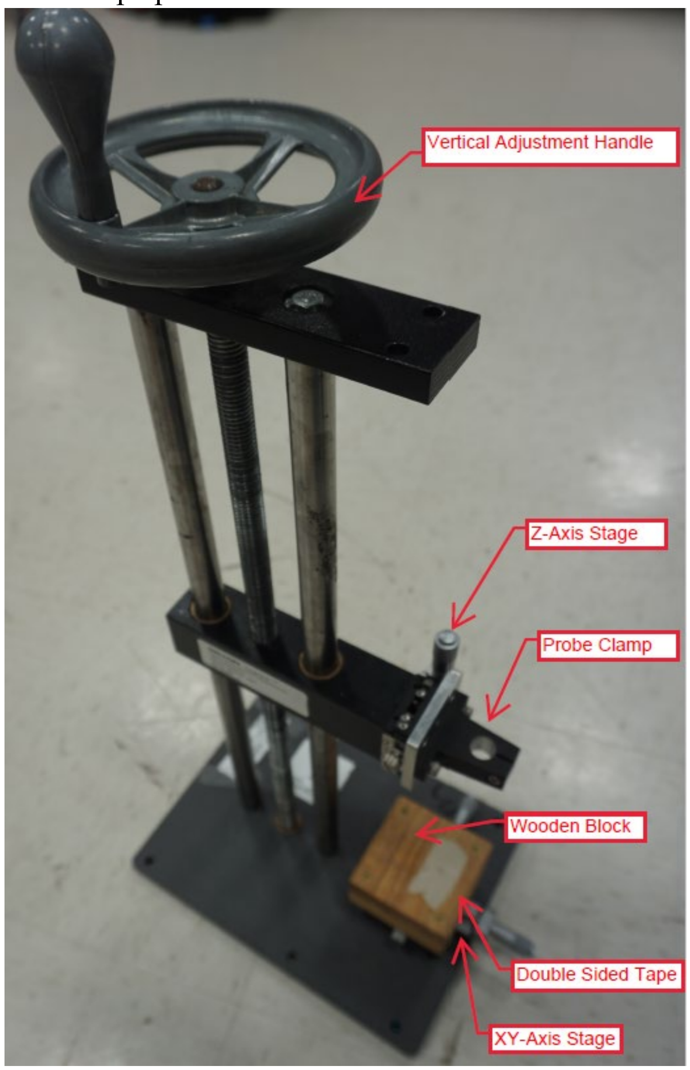

Figure 2: Test Stand Assembly

c. Magnetic field viewer card (Figure 3).

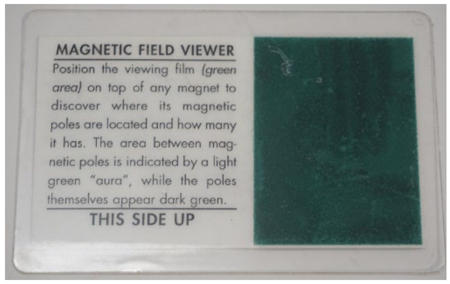

Figure 3: Magnetic Field Viewer Card

d. Calibrated magnets of 750 ± 2% G and 2.6 ± 2% kG (Figure 4).

Figure 4: Calibrated Magnets

e. 4060 zero-gauss chamber, provided by Lake Shore Cryotronics, Inc. (Figure 5).

Figure 5: Zero Gauss Chamber

f. Metal vernier calipers with resolution of 0.1 mm (Figure 6).

Figure 6: Metal Vernier Calipers

g. Stainless steel feeler gauge (0.254 mm) (Figure 7).

Figure 7: Stainless steel Feeler Gauge

3.0 Setup Procedure

a. Use the magnetic field viewer card to locate the magnet's pole. Below are examples of the card identifying the pole of round and rectangular magnets (Figure 8).

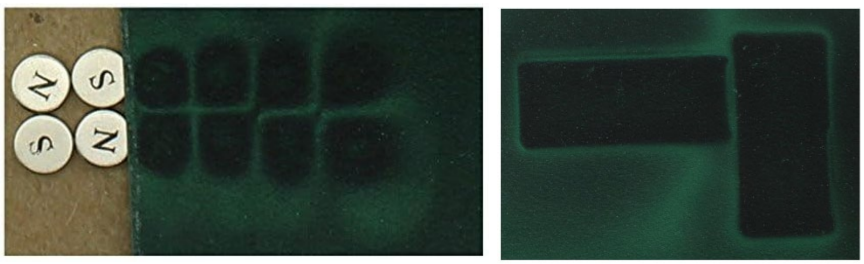

Figure 8: Magnets poles identified.

b. Use the metal calipers to measure and record diameter (d) (mm) of spherical magnet or length (l) and width (w) (mm) of rectangular/cube magnets. Take these measurements in the X, Y and Z planes of the magnet to verify size. Use these measurements to calculate the cross-sectional area of the magnetic pole (mm^2).
   i. Spherical magnetic pole area = $\frac{1}{4} \cdot \pi \cdot d^2$.
   ii. Rectangular/Cube magnetic pole area = $l \cdot w$.

c. Prepare test stand and a new piece of double-sided tape.

d. <u>For spherical magnets</u>: Place the magnet on the flat surface of the metal calipers through its attraction to the calipers (Figure 9). This establishes a vertical pole orientation of the magnet.

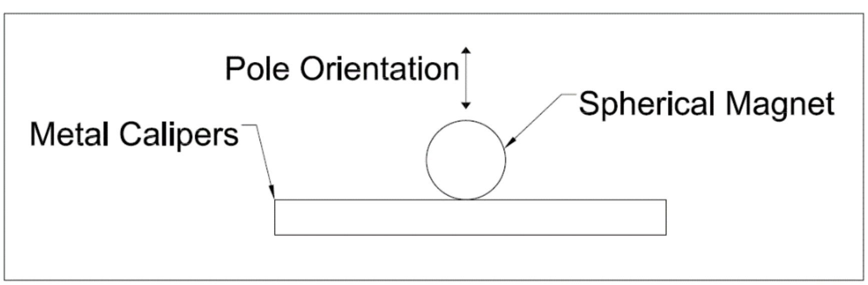

Figure 9: Magnet Placed on Flat Surface of Calipers

e. For spherical magnets: Holding the metal calipers parallel and the magnet facing towards the wooden block/double-sided tape, lower the calipers and press the magnet into the double-sided tape with force to maintain adhesion (Figure 10). Maintain the orientation of the magnet when transferring to the double-sided tape.

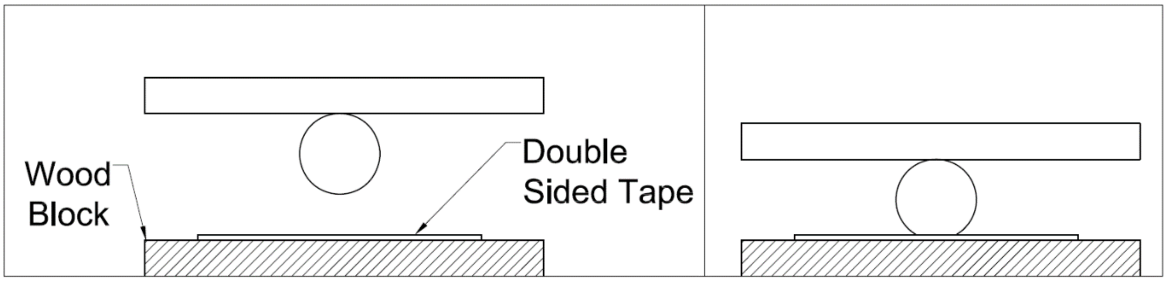

Figure 10: Magnet Pressed into Double-Sided Tape

f. For spherical magnets: Once the magnet is stabilized in the double-sided tape, remove the calipers. Monitor the magnet when lifting the calipers and confirm magnet has not rolled or shifted. The spherical magnet should now be held with the magnetic poles perpendicular to the wooden block surface (Figure 11).

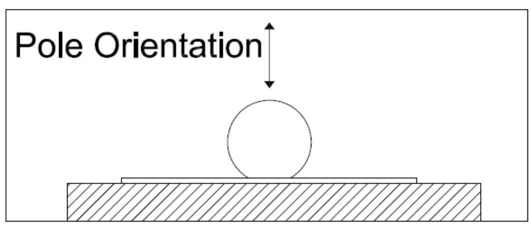

Figure 11: Magnet Transferred to Double-Sided Tape

g. For rectangular/cube magnets: Using the magnetic field viewer card, verify the magnet's pole is facing vertically.
h. For rectangular/cube magnets: Place the magnet onto the double-sided tape while maintaining the magnet's pole oriented vertically.

4.0 Test Procedure and Results

a. Verify calibration is up to date of the teslameter and probe.
b. Verify teslameter is set to direct current (DC).
c. Remove all magnetic sources from the test area.
d. Zero the probe by placing the probe tip within the zero-gauss chamber.
e. Using calibrated magnets, verify gauss readings are within ± 2%.

f. Place the probe within the clamp and arrange the probe tip above the magnet.
g. Record the maximum flux density (kG) in the Z-axis direction. *Note, the maximum flux density reading pulls values from the magnitude reading which is a vector sum of all three axes*.
    i. Adjust the vertical probe position to be 0.254 mm above the magnet using the vertical adjusting stand and feeler gauge.
    ii. Adjust the magnet position under the probe by turning the knobs of the XY-axis table to locate the highest flux density reading in the Z-axis direction.
    iii. Lower the vertical probe position to contact the magnet using the Z-axis stage to locate the maximum flux density in the Z-axis direction. This may take several seconds to allow the reading to reach its highest point.
h. Calculate the flux index (kG^2mm^2) by multiplying the square of the maximum flux density in the Z-axis direction (kG^2) by the area of the pole surface (mm^2).

5.0 Performance Requirement

a. If the magnet fits within the small part cylinder described in 16 CFR 1501.4, the flux index shall be less than 50 kG^2mm^2.