



# Testicool

## Product Design Specifications

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*Product Design Specifications (PDS)*

BME 200/300 Section 301

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## Function

The function of the scrotal cooling device is to maintain the testes at the optimal temperature for spermatogenesis during therapeutic sauna treatment.

## Client requirements

The client has the following requirements

- Maintain scrotum at 92 °F during sauna temperatures between 170°F and 176°F (76.6°C - 80°C) for up to 30 min.
- Establish testing protocol/model to determine testicle temperature during sauna exposure.
- No specific material concerns from a urologic perspective.

## Design requirements

### 1. Physical and Operational Characteristics

#### a. Performance requirements

- i. This device should be capable of maintaining the testes at 34 °C - 35 °C [1] during an up to 30 minute sauna exposure of up to 100 °C [2]

#### b. Safety

- i. The Testicool is expected to fall under Class I medical devices [3], since it is non-invasive, surface-contacting, and low risk. Despite this lower classification, safety remains critical because the device directly interfaces with sensitive genital tissue and must maintain tight temperature control during use. The primary safety concern is preventing testicular tissue damage caused either by excessive heating (if cooling is insufficient) or overcooling (if the device cools below the physiological range for spermatogenesis, 34–35 °C). To address this, the device must reliably maintain scrotal skin temperature within  $\pm 1$  °C of the target.

#### c. Accuracy and Reliability

- i. The device should maintain the testicles within  $\pm 1$  °C of 34.5 °C. Even brief elevations of testes temperature have been shown to decrease sperm viability [4]

#### d. Life in Service

- i. Men's undergarments are generally recommended to be replaced every 6 to 12 months. [5] If our product is a fully wearable undergarment, then 12 months should be targeted. Other designs may allow for longer service lives.

#### e. Shelf Life

- i. The product should not have any major shelf life degradation concerns. Potential electronics included in the product may require charging or battery replacement after prolonged storage.

#### f. Operating Environment

- i. The product will be used inside the sauna with temperatures up to 100 °C [2] with humidities up to 40% [6]
  - g. **Ergonomics**
    - i. The product should be discreet and comfortable to wear. The product should also be wireless or battery-operated.
  - h. **Size**
    - i. Size will need to be adjustable to adapt to the wide range of body sizes. Testicles range in volume from 15-35mL [7]. Men's underwear waist sizes range from 71 cm (28in) for size small to 127cm (50in) for size 3XL [8].
  - i. **Weight**
    - i. Men's undergarments typically weigh between 70g and 100g [9]. To minimize discomfort, the total weight of our product plus any undergarments should be kept below 200g.
  - j. **Materials**
    - i. Given the product's contact on sensitive areas of skin, materials should be chosen to limit the risk of allergic reactions or contact dermatitis. These include azo or anthraquinone-based disperse dyes, triclosan, zinc pyrithione, silver particles, dimethyl fumarate, and isothiazolinones (used as biocides) and nickel, chromium, and cobalt (used as fasteners) [10].
  - k. **Aesthetics, Appearance, and Finish**
    - i. The product should look professional and finished. If electronics are used, loose wires should be organized and hidden whenever possible.
2. **Production Characteristics**
- a. **Quantity**
    - i. Currently only a prototype is planned to be made.
  - b. **Target Product Cost**
    - i. The project has a budget of up to \$1,000. Mass production cost would be aimed at a competitive market price.
3. **Miscellaneous**
- a. **Standards and Specifications**
    - i. The device is classified as a surface-contacting medical device (skin/genital contact, limited/prolonged use). In accordance with ISO 10993-1:2018 [11] and FDA guidance, the following endpoints will be evaluated:
      - 1. Cytotoxicity - Testing ensures that none of the materials in direct contact with the scrotal skin release substances that are toxic to cells, protecting testicular tissue viability.
      - 2. Sensitization - Testing confirms that prolonged wear will not trigger allergic skin responses, such as rashes or delayed hypersensitivity, which is critical in the sensitive genital area.
      - 3. Irritation - Testing verifies that the device materials will not cause redness, burning, or local inflammation during sauna exposure, ensuring wearer comfort and tissue safety.

4. Sample preparation - Ensures that all biocompatibility tests are run on material extracts prepared in a standardized way, providing reliable safety data for the actual device materials.
  5. Additional characterization under ISO 10993-18 and ISO 10993-17 may be considered if chemical analysis identifies potential leachables.
- ii. FDA approval may or may not be required for our product. This is dependent upon our final design.
  - iii. The Testicool is expected to fall under Class I medical devices, since it is non-invasive, surface-contacting, and low-risk.
- b. **Customer**
- i. Customers may have issues with the comfort of the device as well as the rapid loss of cooling [12].
  - ii. Our customer prefers a device that is simple to operate and requires minimal effort to use.
  - iii. Comfortable to wear for up to 30 minutes in a sauna without causing discomfort.
  - iv. Customers would value something proven in a sauna environment with data behind it.
- c. **Patient-related concerns**
- i. The device should be cleaned in between uses to prevent bacterial growth.
- d. **Competition**
- i. The underdog is a cooling pack that is placed below the groin to prevent elevated testicular temperature [13].
  - ii. The uBreeze is a fan-operated scrotal cooling device that is inserted into an undergarment [14].

## References

- [1] A. Jorban, E. Lunenfeld, and M. Huleihel, “Effect of Temperature on the Development of Stages of Spermatogenesis and the Functionality of Sertoli Cells In Vitro,” *Int. J. Mol. Sci.*, vol. 25, no. 4, p. 2160, Feb. 2024, doi: 10.3390/ijms25042160.
- [2] T. Laukkanen, H. Khan, F. Zaccardi, and J. A. Laukkanen, “Association Between Sauna Bathing and Fatal Cardiovascular and All-Cause Mortality Events,” *JAMA Intern. Med.*, vol. 175, no. 4, pp. 542–548, Apr. 2015, doi: 10.1001/jamainternmed.2014.8187.
- [3] C. for D. and R. Health, “Overview of Medical Device Classification and Reclassification,” *FDA*, Nov. 2018, Accessed: Sept. 18, 2025. [Online]. Available: <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification>
- [4] A. Garolla *et al.*, “Seminal and molecular evidence that sauna exposure affects human spermatogenesis,” *Hum. Reprod. Oxf. Engl.*, vol. 28, no. 4, pp. 877–885, Apr. 2013, doi: 10.1093/humrep/det020.
- [5] “Underwear that Lasts: Tommy John’s Guide to Keep Your Skivvies in Shape,” Tommy John. Accessed: Sept. 18, 2025. [Online]. Available: <https://www.tommyjohn.com/blogs/news/how-long-does-underwear-last>
- [6] “The North American Sauna Society,” The North American Sauna Society. Accessed: Sept. 18, 2025. [Online]. Available: <https://www.saunasociety.org/sauna-experience>
- [7] “Testicles (Testes): Location, Anatomy, Function & Conditions,” Cleveland Clinic. Accessed: Sept. 18, 2025. [Online]. Available: <https://my.clevelandclinic.org/health/body/23964-testicles>
- [8] “Comfortable underwear and stylish apparel for the whole family | Fruit of the Loom.” Accessed: Sept. 18, 2025. [Online]. Available: <https://www.fruit.com/size-guide/undefined>
- [9] “How much do clothes weigh?,” Health Service Navigator. Accessed: Sept. 18, 2025. [Online]. Available: <https://www.myhsn.co.uk/top-tip/how-much-do-clothes-weigh/>
- [10] “Allergies caused by textiles: control, research and future perspective in the medical field,” *Int. Immunopharmacol.*, vol. 110, p. 109043, Sept. 2022, doi: 10.1016/j.intimp.2022.109043.
- [11] “ISO 10993-1:2018,” ISO. Accessed: Sept. 18, 2025. [Online]. Available: <https://www.iso.org/standard/68936.html>
- [12] T. Benidir, T. Remondini, S. Lau, and K. A. Jarvi, “Evaluation of patient compliance with the use of scrotal cooling devices,” *FS Rep.*, vol. 2, no. 3, pp. 289–295, Sept. 2021, doi: 10.1016/j.xfre.2021.06.007.
- [13] “How The Underdog Works,” Underdog. Accessed: Sept. 18, 2025. [Online]. Available: <https://underdogfertility.com/pages/how-the-underdog-works>
- [14] “Buy uBreeze - A Handy Testicular Cooling Device,” uBreeze.org. Accessed: Sept. 18, 2025. [Online]. Available: <https://ubreeze.org/product/ubreeze/ze/>