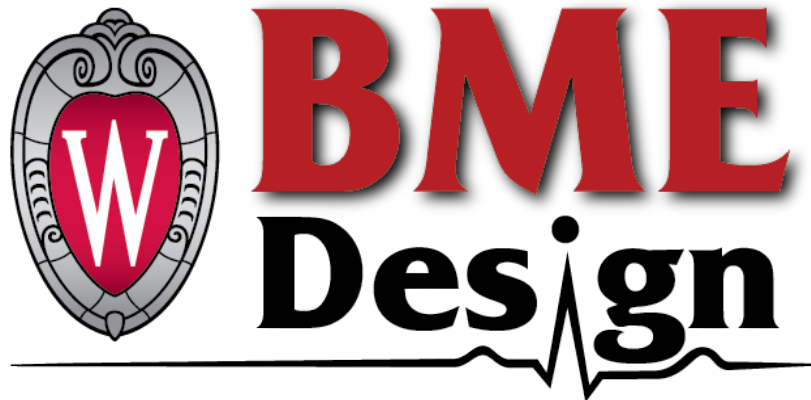




VET Stand

Product Design Specification (PDS)

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Function

This device will allow radiation technicians to secure an animal's teeth and upper jaw into the correct position for radiation therapy. The device will be easily adjustable in both width and height to accommodate a large range of animal sizes, and these adjustments will be easily repeatable, allowing the animal's head to be put in the same position over multiple treatment sessions.

Client requirements

- Bite block stand adjustable to all breeds of dog and cat
- Components able to be adjusted with one hand
- Holds animal's head securely without use of dental putty
- Adjustments can be easily repeated

1. Physical and Operational Characteristics

a. Performance requirements

The bite block will have two round indents, adjustable to intercanine widths ranging from 12–65 mm and height from the table ranging from 0–30 cm [1], [2]. Technicians will be able to use one hand to make these adjustments, and setup for each animal should take under 5 minutes. Each adjustment will have clear markings, allowing the technician to note and recreate the position of each animal over multiple treatment sessions. The device should withstand a downward force of 66 N distributed evenly onto both canine tooth indents [3]. All internal and external elements of the stand should be durable; this device is intended to be used multiple times a day for multiple days in a row, and should maintain its original adjustability and precision.

b. Safety

The FDA does not oversee or require approval for devices intended for animal use; however, care should still be taken to ensure the device does not pose any risk to the patient [4]. The device should be printed using non-toxic filament, and all mechanical elements should be contained or shielded from the area that will come into contact with the animal's mouth to prevent injury. The device must also have clear operation instructions to avoid misuse.

c. Accuracy and Reliability

This device's adjustable components will allow patient positions to be repeatable with a margin of ± 2.5 mm [5]. This device should retain this preciseness regardless of mechanical wear.

d. Life in Service

The stand should last 5 years. The track to control the intercanine distance and height should last 500 uses.

e. Shelf Life

The stand should maintain structural and functional integrity during long-term storage. It should be stored at room temperature, in a dry area, away from large amounts of UV light.

f. Operating Environment

The stand will be used in both areas of diagnostic and treatment of cancerous tumors in cats and dogs. During use the stand will be exposed to X-rays, electron beams, disinfecting agents, and animal bodily fluids. The stand should be designed to withstand corrosion and degradation.

g. Ergonomics

The stand should be able to accommodate cats and dogs of various sizes by allowing adjustment to the height and size of the bite block. The adjusting mechanism should be accessible and easy to use allowing for a single person to adjust without the use of excessive force.

h. Size

The stand will need to be adjustable to heights within the range of 0–30 cm from the table to accommodate cats and dogs of various sizes. The bite block will need to adjust between a minimum size of 12 mm to a maximum size of 65 mm to fit various sizes of cat and dog canines [1], [2].

i. Weight

The stand should weigh no more than 3 kg to ensure that the operator can comfortably transport and operate the stand with one hand [6].

j. Materials

The bite block stand should be made out of carbon fiber PLA to reduce the amount of Z material used.

k. Aesthetics, Appearance, and Finish

The bite block and stand should be white to match other medical devices. The bite block and stand should have a smooth finish.

2. Production Characteristics

a. Quantity

This will depend on the mobility of the stand. If it's mobile on a cart, then a vet clinic would only need one. However, if they are stationary, then they may need one per CT or linear-accelerator.

b. Target Product Cost

There is no client-given budget, as the client will provide PLA and ABS if needed to print the prototype out on 3-D printers. The target product cost should be under \$100 because this product could be mass-produced.

3. Miscellaneous

a. Standards and Specifications

The device will be classified as a veterinary animal device because it is intended to physically position and immobilize dogs and cats during CT imaging and radiation therapy. The FDA regulates animal devices but does not require premarket approval, or establishment registration and device listing for devices intended exclusively for animal use [4]. The device will also follow relevant American Animal Hospital Association (AAHA) veterinary guidelines. The guidelines state that the head and neck should be stabilized when forces are applied in the mouth and that a mouth prop should not fully open the mouth or overextend the temporomandibular joint [6]. Because the device will be used in conjunction with CT imaging, the design should not interfere with the imaging process or introduce unnecessary artifacts into CT images. The FDA regulates CT systems as radiation-emitting products and medical devices, although these requirements primarily apply to CT equipment itself rather than external positioning devices [7]. Current AAHA oncology guidelines for dogs and cats emphasize that radiation therapy requires precise delivery of radiation to a defined target [8]. Therefore, the bite block should provide consistent and repeatable positioning of the animals head and jaw between CT imaging and radiation treatments while minimizing movement during treatment. The device should also be designed so that it does not obstruct the radiation field.

b. Customer

The client specified the need to set up the product quickly. Stands that are currently used require a long time to set up due to using screws to ensure lockage between each platform. The client wants to have an easy adjustable knob to set up the stand in a much quicker time alongside having an unique locking mechanism that prevents the platform from sliding or moving.

c. Patient-related concerns

The device will be designed to minimize discomfort and prevent injury to the animal's teeth, jaw, and surrounding tissues during anesthesia. The bite block should apply enough force to securely position the jaw without causing excessive pressure or jaw pain, and it should accommodate differences in jaw size between dogs and cats. The device should not interfere with the endotracheal tube or place pressure, tension, or displacement on the tube while the animal is positioned. Because the device will be used between multiple animals, it should be made from materials that can withstand sterilization or appropriate disinfection between uses without degrading. The device should also have smooth, non-irritating surfaces and minimize areas where saliva, blood, or other biological material could accumulate.

d. Competition

The client mentioned similar 3D designs online with a knob system that adjusts the height of a phone stand, and wants the design to have a similar mechanism. The knob must be pulled to be able to twist. Otherwise, the knob stays in place and can not be turned to ensure no random movement.

Citations

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