

Dignitana understands that each hospital has its own cleaning procedures to follow for equipment, however Dignitana recommends hospitals follow the cleaning recommendations outlined below. If other cleaning products or procedures are used Dignitana cannot guarantee the quality of the product.

Cleaning

DigniCap Delta Device

There are two recommended methods to clean DigniCap Delta:

1. Germicidal disposable wipes (non-bleach)
2. 70% alcohol or alcohol wipes

DigniCap Delta should be cleaned after each use.

DigniCap Delta Cooling Wrap and Thermal Cap

The Cooling Wrap and Thermal Cap are designed for single patient use.

Clean exposed surfaces of the Cooling Wrap and Thermal Cap with a mild anti-bacterial soap and water solution, an isopropyl alcohol and water solution or an anti-bacterial wipe. Do not use bleach.

The wrap and cap should be separated after each use and stored in a mesh bag to dry. The Cooling Wrap and Thermal Cap should not be exposed to extreme temperatures. Store between 50-80 F (ambient). Do not store in places such as a car or garage.

The cleaning recommendations for The DigniCap Scalp Cooling System were reviewed and cleared by the FDA. Upon review it was found that the risk with multiple uses after cleaning is acceptable and is comparable with other similar nonsterile medical devices e.g. reusable blood pressure cuffs with the same cleaning instruction or mechanically cleaning on a smooth surface.

Handling

DigniCap Delta should be handled carefully and stored in a dry, well-ventilated place. The device should be stored plugged in and turned on in order to charge the battery while not in use.



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