



TESTING PROTOCOL FOR THE MILITARY AND/OR BIOMED DEPARTMENTS

MODEL #: CT-1000, CT-1010, and CT1010-A

The CryoPen has no user serviceable parts inside and the only preventive maintenance needed is listed in the Operator's Manual.

The CryoPen System consists of a specially designed low temperature cooler, power supply, cold plate, medically designed hand-held modules, temperature indicator, and a special enclosure. When these components are properly installed and system is turned on, the unit will reach its operating temperature in approximately 90 minutes.

The time to reach the same temperature if a warm pen is inserted into a pen receptacle (chilling well) of an operating cooler is approximately 10 minutes.

The unit must never be allowed to operate without three CryoPens (hand-held modules) inserted into the three available receptacles (chilling wells). When removing a cold pen preparatory to using it in a clinical procedure, the emptied receptacle should be quickly filled with a warm pen.

Note: Pens should always be wiped dry and dipped into the Reservoir Solution before inserting in open receptacle (chilling well). Failure to follow these guidelines will allow moisture from the ambient air to freeze out on the very cold surfaces (CryoPen chilling wells) of the cold plate (that part of the system which actively cools the pens in their receptacles). If an ice build-up is allowed to occur, the system must be turned off and the moisture removed from the previously iced-up socket.

If an independent reading of a CryoPen Hand-Held Module temperature is desired, then proper wire type, polarity and mating connector must be prepared. The meter used to read the temperature must be capable of reading to -100 degrees Celsius. Many less expensive units will not do this. CryoPen can provide the part number and schematic for preparing the connecting wire for this test if required by your organization/facility.

Pen Temperature reading when CryoPen temperature indicator reads green: colder than -75 Celsius

Standard Set point temperature of the CryoPen System when operational: -75 to -101C

Validation that the CryoPen is in compliance is done by the temperature indicator, as per operator's manual. As long as it indicates green, system is working properly.

Battery life of the temperature indicator under normal conditions is estimated to be 5 years, at which time it should be returned to CryoPen for a replacement battery.