

## **G. Hygiene and maintenance**

### **The Krystal-X box**

The Krystal-X box does not require any specific maintenance. The Krystal-X Wifi box should be cleaned using a cloth and non-abrasive detergents.

### **The Krystal-X sensor**

It is essential that the Krystal-X sensor be barrier protected by using a disposable FDA-cleared barrier (bag/sheath) to reduce cross contamination during use (some protective sheaths are initially provided with each system). Before each use, the sensor must be placed inside the protective sheath.



After each use on a patient, throw away the protective sheath and disinfect the sensor applying a high level disinfection procedure (see below).

A new protection must be used for each new patient.

We recommend that these hygienic protections be disposed of with the practice's other biologically dangerous waste.

Examples protections that are valid for North America: BANTA HEALTHCARE or TIDI PRODUCTS X-ray sensor sheaths, STERI-SHIELD PRODUCTS RS barriers.

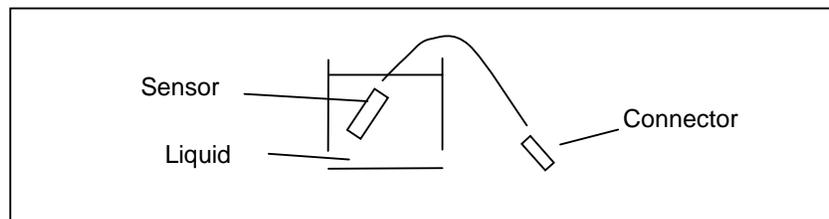
### **Recommended disinfection procedure**

The sensor being watertight, to minimize the potential for device-associated infections, the device shall be disinfected with in a FDA-cleared high level disinfection agent following the instructions of the manufacturer for use, storage, handling and warning.

The following disinfectant agent has been validated with the Krystal-X sensor: CIDEX OPA solution (0.55% Ortho-phthalaldehyde solution). The max soaking period is 24 hours.

### **Procedure**

Remove the hygienic protective sheath (dispose of it appropriately with contaminated waste). Vigorously wipe down the sensor to remove any visible soil. If necessary, rinse it with copious amounts of water. Then, place the sensor in the disinfecting agent.



Immerse only the sensor and the beginning of the cable in the disinfectant for 15 min; never immerse the connector in the liquid. Then, rinse thoroughly the sensor with copious amounts of fresh water.

In case it is not being used immediately upon rinsing, as in the case of allowing it to air-dry over night at the end of a work day, the sensor should be rinsed with sterile water.

### **CAUTION**

**Never leave the Krystal-X sensor to soak for longer than is necessary.**

**As the Krystal-X sensor consists of an electronic circuit; it must not be sterilized in an autoclave. The high temperature and excessive high pressure will lead to damage of the sensor.**

**The connector of the Krystal-X sensor to the Krystal-X control box must not be immersed.**

### The positioners

For the positioners supplied with the system follow the same cleaning and disinfecting instructions as the sensor (see previous paragraph).

When using a positioner, the hygienic protective sheath shall include both sensor and positioner.