Installation and Care Instructions for EVA SELECT and EVAsoft

1.0 UNPACKING YOUR EVA SELECT SYSTEM:

1.1 Contents:
- 1 EVA Select Sensor (either Size #1 or Size #2)
- 1 Docking Station
- 1 USB Cable
- 1 USB Flash Drive with sensor configuration files.
- Starter Kit of hygienic protective barriers.
- RINN XCP-DS aiming aids/sensor holders.
- EVAsoft Software installation CD

2.0 INSTALLATION INSTRUCTIONS:

- Plug the Flash Drive (packaged with the sensor) into the computer. After the driver loads, right mouse click on and run as administrator the RunInstall.cmd file located on the Flash Drive. Repeat this step for each sensor that will be used with this computer.
- When instructed, plug the EVA SELECT sensor, the docking station and the USB cable into your computer’s USB Port. Allow the Windows Hardware Wizard to run. NOTE: the Windows Hardware Wizard may take a minute or two to complete.
- Install EVAsoft from the CD provided.
- Launch EVAsoft.
- In the Image Devices Menu, choose EVA SELECT (this is only required the first time).
- Select a patient.
- Enter the Acquire Tab.
- Press ENDO or Series mode button.
- Wait while the sensor initializes until the acquire status is GREEN “ready for x-ray”.
- Position the sensor and continue with your x-ray imaging.
3.0  CARE INSTRUCTIONS:

3.1  **General precaution:** The EVA SELECT dental intra-oral X-ray sensor is a sophisticated electronic product incorporating advanced technologies. As such, it is to be handled with a high degree of care. Moreover, by design, the EVA SELECT dental intra oral X-ray sensor cannot be used in certain conditions.

**NOTE:** This device cannot be used in an anesthetic gas environment.

3.2  **Cleaning instructions:** Ensure that ALL personnel who use or handle the sensor carefully read and understand the cleaning and disinfection instructions below. Following these recommendations will allow you to clean the sensor safely.

3.2.1  **Recommended practices:**

- **The EVA SELECT dental intra-oral X-ray sensor is NOT supplied as a sterile medical device.** Disinfect the sensor before first use and subsequently before use with every new patient.
- Always use protective gloves when using, cleaning or disinfecting the sensor.
- Use a new disposable protection barrier with every sensor usage. This protection must be biocompatible following the standard ISO 10993-1.
- Clean the sensor by wiping the sensor’s head and the first 5 inches (10 cm) of the sensor cable with a compress moistened with a disinfecting solution.
- Disinfect the sensor by immersing in a disinfecting solution. Please read and follow the manufacturer recommended immersion time. **DO NOT** immerse the sensor if there are nicks or deep scratches on the sensor head. Only immerse the sensor head and cable, **NOT** the gray plastic connector section.

3.2.2  **Warnings:**

- **The EVA SELECT dental intra-oral X-ray sensor is not designed for high temperatures.** **DO NOT** sterilize the sensor using an autoclave or a UV oven.
- The sensor housing and the cable are made out of plastic materials. *Bleach or alcohol content solutions will damage them.* Please refer to the recommended disinfecting products list below.
- The sensor head and the cable are watertight, but the gray connector section is not. **DO NOT** immerse the gray connector section in disinfectant for cleaning
- The sensor housing is fragile. **DO NOT** clean using inappropriate instruments.
3.2.3 **Recommended disinfecting solutions:**

Do not use aggressive products that may degrade the sensor.

- **Preferred disinfectants:**
  - ANIOXY TWIN™ (ANIOS Laboratories)
  - PHAGOCID D™ (PHAGOCENE DEC. Laboratories)

- **Other authorized disinfectants:**
  - CIDEX OPA™ (JOHNSON & JOHNSON)
  - DENTASEPT ultra™ (ANIOS Laboratories)
  - RELYON PERASAFE™ (Phagogene DEC. Labs)

- **Forbidden products:**
  - ALCOHOLS (Isopropyl Alcohol, Methanol)
  - SEKUSID-N™ (ECOLAB PARAGERM Laboratories)
  - SEKUSEPT Easy™ or Aktiv™ (Ecolab Paragerm Labs)
  - FD333™ or FD322™ (DÜRR DENTAL Laboratories)

3.3 **Instructions for use and handling:** Please ensure that ALL personnel who use, handle, or work around the sensor carefully read and understand the instructions below. Following these recommendations will ensure you handle the sensor safely and prevent shortening of the sensor’s lifespan.

3.3.1 **Recommended practices:**

HANDLE:

- **Always handle and manipulate the sensor with utmost care.**
- Plug and unplug the sensor holding the gray plastic connector (not the cable).
- Ensure that the sensor head never strikes a hard surface (for example falls to the floor from a counter).
- **NEVER** pull the cable, always carefully lift the sensor head.
- Ensure that the cable is not tangled when in use.
- **DO NOT bend the cable too severely** as this can cause permanent damage to the sensor.

DISPOSABLES:

- Use the holders (i.e., aiming aids), protection barriers, and other disposables supplied with the sensor or recommended by your dealer.
- Always use the sensor with a holder and protection cap of the proper size.
- To remove the sensor from the holder, grip the sensor carefully and withdraw holder (do not pull the sensor out by the cable).
3.3.2 **Warnings:** While in use, most accidental damage to the sensor occurs when the cable is lying on the floor or is run across a hallway or other passageway.

**Configuration:**
The sensor installation should be configured in order to avoid:
- Cables lying on the floor when in use.
- Running cables across a hallway or other trafficked area.

**Handling:**
The following handling errors could damage your sensor permanently:
- Severely pinching the sensor or cable (ex: cable pinched in a drawer).
- Pulling or bending the cable severely.
- Unplugging the sensor by pulling the cable.
- Dropping the sensor (see above).
- Rolling over the cable with a chair or walking over it (see above).
- Biting the sensor or cable.

The following handling errors could be harmful to the operator and/or the patient:
- Connecting or disconnecting the sensor while the electronic interface is powered up.
- Touching the connector pins.
- Getting liquid on the connector (for example during cleaning).
- Using a sensor which is nicked, cracked, deeply scratched on the sensor’s head or on the cable or otherwise obviously damaged.

**Disposables:**
The following handling errors could damage your sensor permanently:
- Removing the protection barrier by pulling on the cable.
- Coiling the cable around the holder during use.

3.4 **Instructions for storage:** Please carefully read and follow the instructions below to ensure you handle the sensor safely and do not shorten the sensor’s lifespan.

3.4.1 **Recommended practices:**

**Sensor storage between 2 exposures:**
- Leave the sensor plugged into the PC.
- Store the sensor in a holder (or on a hook) fixed on the wall.
• Coil the cable in large loops (1 or 2 loops) in order to avoid the cable lying on the floor.

Sensor storage between 2 patients (or for the night):
• If possible, leave the sensor plugged into the PC (same as above).
• If you have to move the sensor to another room:
  o Unplug the sensor carefully.
  o Coil the cable in large loops in order to avoid the cable lying on the floor.
  o Store the sensor in a holder or on a hook fixed on the wall.
• If you have to store the sensor on a shelf or drawer, package the sensor well to provide cushioning and avoid shifting. Make large loops with the cable (9 inches or 20cm in diameter if possible).

3.4.2 Warnings: When not in use, most accidental damage to the sensor occurs when the sensor falls off a counter or the cable is too tightly coiled.

Please make sure to avoid the following configurations:
• Using a very tight box to store the sensor.
• Storing the sensor freely on a table, countertop or a shelf.
• Running, or looping the cable near or over drawers (you could pinch the cable).
• Storing several sensors on the same hook.
• Curling the cable in tight loops (for example around the gray plastic connector).
• Running over the cable with chair wheels.
• Catching a loop of the cable in a chair leg.

4.0 DISPOSAL INSTRUCTIONS: The sensor head contains potentially hazardous substances (material of the scintillator). It must to be treated specifically at disposal. The cable and connector have to be recycled as electronic waste.

5.0 ADDITIONAL INFORMATION: Additional information can be found in the EVAssoft User Manual supplied with EVAssoft or on our website at www.ImageWorksCorporation.com.

6.0 CONTACT AND SUPPORT: For additional information and support please contact your dealer or installer. If you feel that information is missing from this document or that the product or instructions supplied by ImageWorks can be improved, please email ImageWorks at support@imageworkscorporation.com or contact ImageWorks online at www.imageworkscorporation.com/technicalsupport.