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NOTICE

Although we have tried to emphasize through our product literature, training and announcements that only QSA Global-manufactured sources and components are tested and endorsed for use in our devices, we find that (1) third party components continue to be used during maintenance of Sentinel TM brand radiography projectors, and (2) third party source assemblies continue to be loaded into these devices. OSA Global, therefore, issues the following notice:

- Use of non-OEM components for repair or maintenance of the Sentinel TM 880 series projectors invalidates the Type B certification of that device. The use of non-OEM components on an 880 series projector also invalidates any warranty stated or implied by QSA Global, Inc. for the device.
- Use of non-OEM sources in the 880 series projectors will likely lead to accelerated wear of the stube within the device and could result in a significant compromise to safety or source retrieval incident due to disconnect or pigtail failure.
- 3rd party sources and accessories have not been tested by QSA Global, and may invalidate the ISO 3999 certification when used with the model 880.
- Improper maintenance of Sentinel TM brand projectors and accessories will lead to accelerated wear and premature failure of these devices.

QSA Global, Inc. has not tested or authorized the use of any third-party-supplied source assembly in the model 880 series projectors, nor does QSA Global supply source holders to third-party vendors for use in the manufacture of their sources (we do selectively supply such holders to our authorized distributors).

The following models are the only QSA Global-authorized source assemblies for use or transport in the 880 series projectors:

A424-9 or A424-23 with Ir-192 A424-25 or A424-25W with Se-75 *A424-19 with Co-60

A424-30 or A424-31 with Cs-137 91807, 91808, or 91810 with Yb-169

*Note: the model A424-19 is no longer manufactured.

QSA Global-manufactured source assemblies have been subjected to extensive testing in accordance with ISO 3999 "Radiation Protection – Apparatus for Industrial Gamma Radiography – Specifications for Performance, Design and Test". This testing included a 50,000 cycle endurance test, tensile test of the source to drive cable connections and tensile test of the swage crimping the source connectors to the Teleflex wire. These tests were performed in a controlled manner, are fully documented and the satisfactory test results have served as the basis for the U.S., Canadian and International Regulatory approvals we have for our sources and projectors.

Differences in source assembly dimensions (diameter, length) from those of the authorized assemblies can contribute to premature wear of the source assembly and/or titanium S-tube within the device, as well as potentially cause the dose rate on the surface of the projector to exceed the maximum allowed by the standards and regulations. Figures 1 and 2 are an example of one such unauthorized assembly:

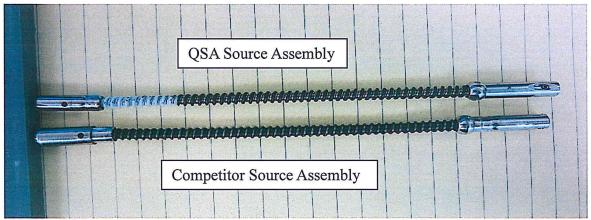


Figure 1

The shorter competitor's assembly length seen in Figure 1 may cause an increase in dose levels in a Model 880 projector since the source is no longer in the maximally shielded position within the projector.

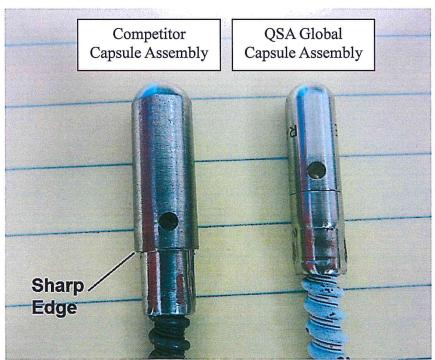


Figure 2

Note in Figure 2 the much larger diameter of the competitor source assembly, the sharp trailing edge, and overall length. The maximum dimensions of a QSA Global Ir-192 source assembly ensure that the source can pass through the projector without damage to either the source channel or source capsule. This particular competitor source is over a millimeter wider and 4 millimeters longer. The larger capsule dimensions, combined with the sharp edge, will contribute to premature wear of the S-tube within a model 880 projector.

Figure 3 shows a comparison between a QSA Global source pigtail and 2 other competitor source pigtails that are presented to the market as equivalent to the QSA Global model.

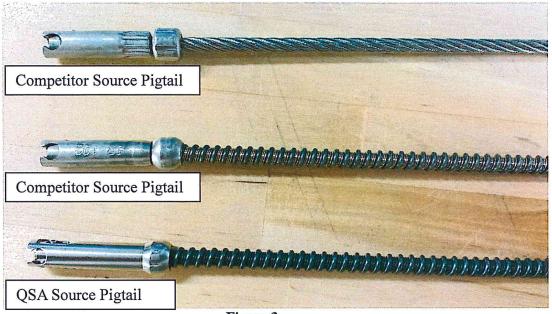
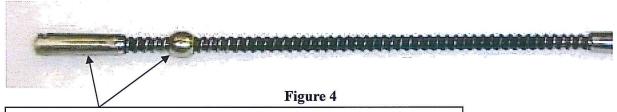


Figure 3

There are many critical characteristics and tolerances on the QSA Global female connector that ensure its positive locking capability for the continued safe operation of the device. A recent event in Texas underlines the dangers of using a non-OEM source assembly in a QSA Global model 880: the stop ball of a 3rd party source slipped on the Teleflex wire preventing the source from being secured in the fully shielded position.



2-Piece Connector. Note that the gap between the connector and the ball has been exaggerated to clearly show the failure condition.

Finally, the use of aircraft cable in lieu of Teleflex cable can lead to the occurrence of 'bird-caging' (an example of which can be seen in Figure 5).



Figure 5

In addition to the use of third-party sources, the use of non-OEM repair components on QSA Global manufactured devices is not authorized, as these components will invalidate the regulatory approvals, as well as the warranty, for the associated device. **IMPORTANT:** A model 880 series projector that has been repaired with aftermarket components cannot legally be shipped as a Type B container. The model 880 series projectors are integrated systems where each component directly influences the integrity and reliability of all the working parts. The system designs are such that component material specifications and tolerances are interrelated. Controlled manufacture to within these tolerances is critical to the safe and proper operation of the projector and accessories. Model 880 series projectors manufactured to these tolerances and specifications were tested to the requirements for Type B transport containers, and the satisfactory test results are the bases for the Type B certification.

QSA Global manufactured equipment and source assemblies are designed, built and tested in strict accordance with our ISO 9001 accredited QA system. Model 880 projectors, when maintained with OEM parts and used with QSA Global-authorized source models, have an excellent safety record world-wide.

Third-party suppliers do not have the detailed knowledge of the 880 series projector system and therefore cannot ensure all the safety and reliability aspects of the system are considered if the device were to be loaded with a source holder of their manufacture or repaired using non-QSA Global supplied parts.

Last, it is critical that QSA Global manufactured devices are inspected, operated and maintained in accordance with the instructions found in the associated Operations & Maintenance Manual. Proper maintenance will ensure continued safety during use of the device, as well as prolonged working life of the device.

Please note that, as stated earlier, the model 880 series projectors, when maintained with non-OEM parts, cannot be transported legally while containing a Type B quantity of radioactive material (e.g. greater than 1 TBq (27 Ci) of Ir-192 or 3 TBq (81 Ci) of Se-75). Additionally, as the design authority for the model 880 series projectors, QSA Global, Inc. is unable to support or endorse the use or transport of a third-party supplied source assembly in these devices as it is not known how it would perform or indeed whether it meets international standards.

If you would like any additional information, please feel free to contact me and I will be glad to assist.

Date: 18 APRIL 2017

Michael Fuller, Director

Regulatory Affairs/Quality Assurance

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