



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

DEC 10 1978

CERTIFICATE OF REGISTRATION
AND SAFETY ANALYSIS SEALED
SOURCE

CORRECTED COPY

Manufacturer and Distributor

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

Sealed Source Model Designation

AMS-3800 Series (ANSI 77E53524)
(See Enclosure 1)

Isotope

Cobalt-60

Maximum Activity

13,680 Curies

Conditions of Normal Use

The AMS-3800 series sealed sources are designed for use in shielded exposure devices for teletherapy or industrial radiography. The medical teletherapy sources will be used at ambient hospital conditions while the industrial radiography sources may be used at temperatures from 0°F to 110°F and in dusty (as in foundry) but dry conditions.

Sealed Source Description

Cobalt-60 metal is doubly encapsulated in heliarc welded stainless steel (#316LC). The outer dimensions of the double capsule are 3.3 cms in diameter x 3.8 cms in height for cobalt-60. Wall thicknesses of the inner and outer capsules are 20 mils or greater. The double capsule is then fitted into an international standard source holder. The active diameters of the cobalt-60 sources vary from 1 cm to 3.0 cm. A tungsten liner of variable diameter is used to fill the excess space inside the double capsule. Thus a source with a given active diameter may produce slightly higher head leakage levels than the same strength source with a small active diameter (see Enclosure 1).

Prototype Testing

Prototype testing of two sources containing 20 gm of cobalt-59 (in place of cobalt-60) was performed in accordance with the recommendations contained in ANSI N542-1977, "Classification of Sealed Sources" (see NBS Handbook 126). The testing was performed by the Herron Testing Laboratories, Inc., and the test data showed that Model AMS-3800 series qualifies for an ANSI N542-1978 classification of ANSI 77E53524.

External Radiation Levels

The maximum radiation levels in air at 5 cm and 30 cm from the source are approximately 540 R/hr and 15 R/hr per curie contained respectively.

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Quality Assurance and Control

Advanced Medical Systems, Inc. stated that their quality assurance program will meet the guidelines outlined in ANSI N542-1977. The leak testing procedure of the inner capsule as defined in paragraph A2.2.2 and the wipe test of the outer capsule as defined in paragraph A2.1.1 both of ANSI N542-1977, are used to determine the integrity of each source.

Certifications

Wipe Test - A certificate is prepared for each source indicating the quantity of contamination removed during the wipe test. This certificate also gives the model number, the serial number of the source, and the date wipe tested.

Calibration - A certificate is prepared for each source indicating the source serial number, the output in Rhm, the type of device in which it is to be mounted, the type of collimating device and settings, and the date calibrated. The contained curies and date of assay are also included on this certificate.

Limitations and/or Other Considerations

- A. This source shall be distributed only to specific licensees of the NRC or Agreement States.
- B. Leak Testing - This source shall be leak tested at six (6) month intervals using techniques approved by the licensing authority.
- C. This source shall not be subjected to environmental or other conditions of use which exceed its ANSI classification 77E53524 (ANSI N542-1977).

References

This certificate of registration of the AMS-3800 series sealed sources is based on information submitted by Advanced Medical Systems, Inc. in their letters dated July 9, 1979, and October 23, 1979 and enclosures thereto.

Date: December 5, 1979

Reviewed By: Paul A. Wacht

Date: December 5, 1979

Concurred By: James W. Burroughs

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LICENSEABLE PRODUCTS

AMS, INC. CAT. NO.	PICKER CORP. CAT. NO.	COMMON GENERIC NAME	COMMON DESCRIPTION OF UNIT
AMS-3800	P-3800-A	Cobalt Source	Double encapsulated ⁶⁰ Cobalt teletherapy and radiography source in International standard source holder. Active diameter 1 cm.
AMS-3801	P-3801-A	Cobalt Source	Same, except 1.5 cm active diameter
AMS-3802	P-3802-A	Cobalt Source	Same, except 2.0 cm active diameter
AMS-3803	P-3803-A	Cobalt Source	Same, except 2.5 cm active diameter
AMS-3804	P-3804-A	Cobalt Source	Same, except 3.0 cm active diameter