

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
(AMENDED IN ITS ENTIRETY)

NO.: NR-0446-D-103-E DATE: December 3, 2015

PAGE 2 of 7

DEVICE TYPE: Timepiece

DESCRIPTION:

Models 100/1, 100/2, 100/3, 100/4 and 100/5 timepieces use gaseous tritium light sources to enable the wearer to read the timepiece dial in low or no light situations. These devices incorporate design and construction features of the former Models P375, P550, P600, P650, and have been redesignated as the Models 100/1, 100/2, and 100/3 to distinguish between the timepiece type for simplicity purposes. Model 100/1 timepieces are analog watches with mechanical or quartz movement. Model 100/2 timepieces are digital watches with liquid crystal display (LCD). Model 100/3 timepieces are watches with analog reading and LCD display. The Model 100/4 timepiece is an alarm clock which is equipped either with mechanical or quartz movements, and analog or digital LCD display. The Model 100/5 timepiece is a pocket watch which is equipped either with mechanical or quartz movements, and analog or digital LCD readout.

Previously, the timepieces were approved for up to 78 mCi (2.9 GBq) tritium in 15 mb-microtec Model 400/1 gas sources (12 sources in the hour positions, one source (one additional in the rotating bezel). All models may contain up to 100 mCi (3.7 GBq) tritium in 1 to 80 mb-microtec Model 400/1, 400/2, or 400/3 sources. Digital LCD timepieces may only need one source for illumination where additional sources may be needed to illuminate additional functions of newer timepiece styles. However, up to two Model 400/1 sources will be used for illumination of the timepiece hands (analog reading). The designing construction of specific timepieces within each Model designation may vary, but will be in accordance with the designs of the former Models P375, P550, P600, P650, including:

- Materials for the case and bottom plate may include one or more of the following: brass, stainless steel, titanium, gold, platinum, injection molded plastic and polymers. Case bottoms may be snap-on, screw-on, or attached by screws.

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
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NO.: NR-0446-D-103-E DATE: December 3, 2015

PAGE 3 of 7

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DESCRIPTION (Cont.):

- Acrylic, sapphire, and mineral glass crystals, secured by a press-fit stainless steel or aluminum ring. Removal of the crystal requires a special tool normally available only in timepiece factories or repair shops.
- Unless the timepiece is destroyed or the crystal removed, there is no access to the sources. Although the case bottom may be removed, the design and construction is such that access to the sources on the hands and dial is not possible without destruction of the timepiece.
- Timepiece hands are specially designed to permit attaching a source from below by a non-hardening adhesive.
- Sources are attached to the dial by either placing them into milled slots and securing them with non-hardening self adhesive, or by a source retaining ring that, when bonded to the timepiece dial, secures the sources in place.
- Timepieces may contain a rotating bezel, with or without a light source. Light sources mounted external to the cases and crystal (such as in a bezel) will be secured and protected from damage by a metal housing and crystal, as described above.

DIAGRAM:

See attachments 1-6

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
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NO.: NR-0446-D-103-E DATE: December 3, 2015

PAGE 4 of 7

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LABELING:

The dial face is marked with "T" (for tritium) as recommended in "Radiation Protection Standards for Gaseous Tritium Light Devices" Section 7 - Marking and Labeling (Nuclear Energy Agency, OECD, 1973). The bottom is marked by etching with "3H" for the contained tritium and with "mbm" for the manufacturer's logo.

CONDITIONS OF NORMAL USE:

The expected useful life of the timepiece is 10 years. The timepiece will be subjected to environs allowing human occupancy.

PROTOTYPE TESTING:

The manufacturer has subjected prototype timepieces to the requirements of ANSI N540. The prototype timepieces passed the requirement for classification T2GC122222.

EXTERNAL RADIATION LEVELS:

External Radiation dose rates are minimal and need not be considered. Primary tritium beta rays do not penetrate the GLTS glass enclosure. Traces of very soft (a few keV) secondary Bremsstrahlung are absorbed by the timepiece case.

Potential doses for LCD timepieces with GLTS backlighting of the display have been estimated and are reported in NUREG/CR-0215, ORNL/NUREG/TM-255 "Estimates of Potential Radiation Doses from Wristwatches Containing Tritium Gas" by McDowell-Bayer and O'Donnell.

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
(AMENDED IN ITS ENTIRETY)

NO.: NR-0446-D-103-E DATE: December 3, 2015

PAGE 5 of 7

DEVICE TYPE: Timepiece

QUALITY ASSURANCE AND CONTROL:

Mb-microtec has specified the following quality control test on production lots of the timepieces.

SOURCE TESTING

All (100%) of the source used are tested for tritium leakage and must pass the soaking test per ANSI N540, section 8.3.2. Lots 1 to 20 sources are accepted when total leakage is less than 50 nCi (1.85 kBq) in 24 hours.

LOT TESTING OF FINISHED TIMEPIECES

All finished timepieces are subjected to a 100% visual inspection for missing, dislodge, dim or black light sources. In addition, a random sample of each finished lot is subjected to the following: a visual inspection for the "H-3" and "mbm" on the timepiece; a drop test from 3.27 feet (1m) to a steel plate, then visual inspection for missing,

dislodge, dim, or black light sources; and a soak test per section 8.3.2 of ANSI N540 to a maximum of 50 nCi (1.85 kBq) in 24 hours. Any failure will trigger a 100% inspection of the lot for the defect.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The import of the device is subject to the provisions of Section 110.27, 10 CFR Part 110.
- These devices may be distributed to persons exempt from the requirements for a license as defined in Section 30.19 if manufactured and initially transferred in accordance with a

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
(AMENDED IN ITS ENTIRETY)

NO.: NR-0446-D-103-E DATE: December 3, 2015

PAGE 6 of 7

DEVICE TYPE: Timepiece

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

specific license issued pursuant to 10 CFR, section 32.22.
This license shall only be issued by the NRC.

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information submitted, we continued to conclude that Model 100/1, 100/2, 100/3 (formerly P375, P550, P600, P650), 1004 and 100/5 timepiece designs are acceptable for licensing purposes. Furthermore, we continue to conclude that these timepiece models would be expected to maintain their integrity under the conditions associated with their intended use.

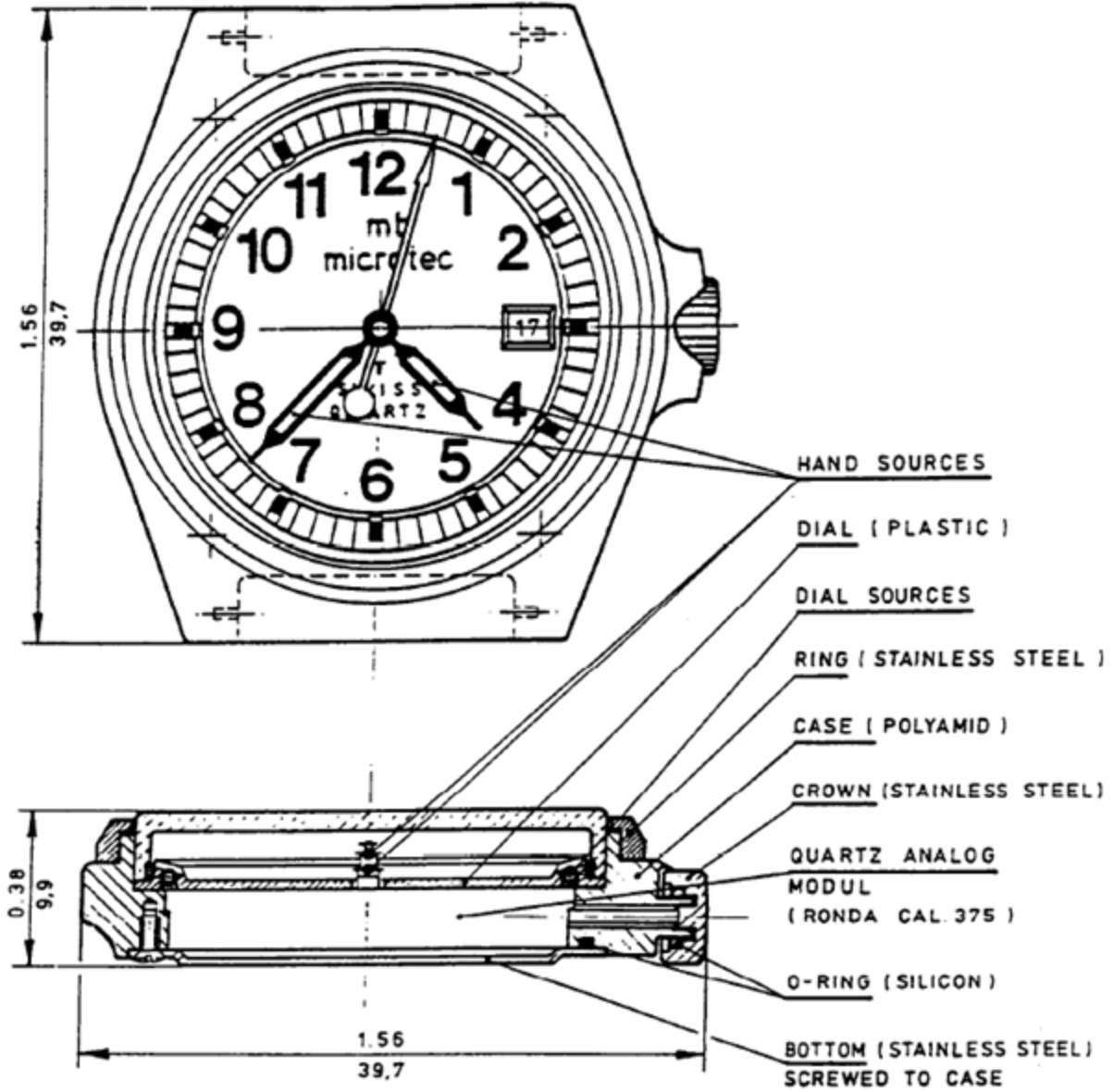
REFERENCES:

The following supporting documents for the Models 100/1, 100/2, 100/3 (formerly P375, P550, P600, P650), 100/4 and 100/5 timepiece designs are hereby incorporated by reference and are made a part of this registry document.

- Mb-microtec's letters dated June 19, 1987, July 23, 1987, June 27 1991, August 30, 1991, October 20, 1993, January 13, 1994, November 10, 1994 December 21 1994, July 18, 1995, January 11, 1996, and September 5, 1996, with enclosures thereto.
- Mb-microtec's faxes dated February 14, 1995, September 17, 1996, and October 22, 1996, with enclosures thereto.

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
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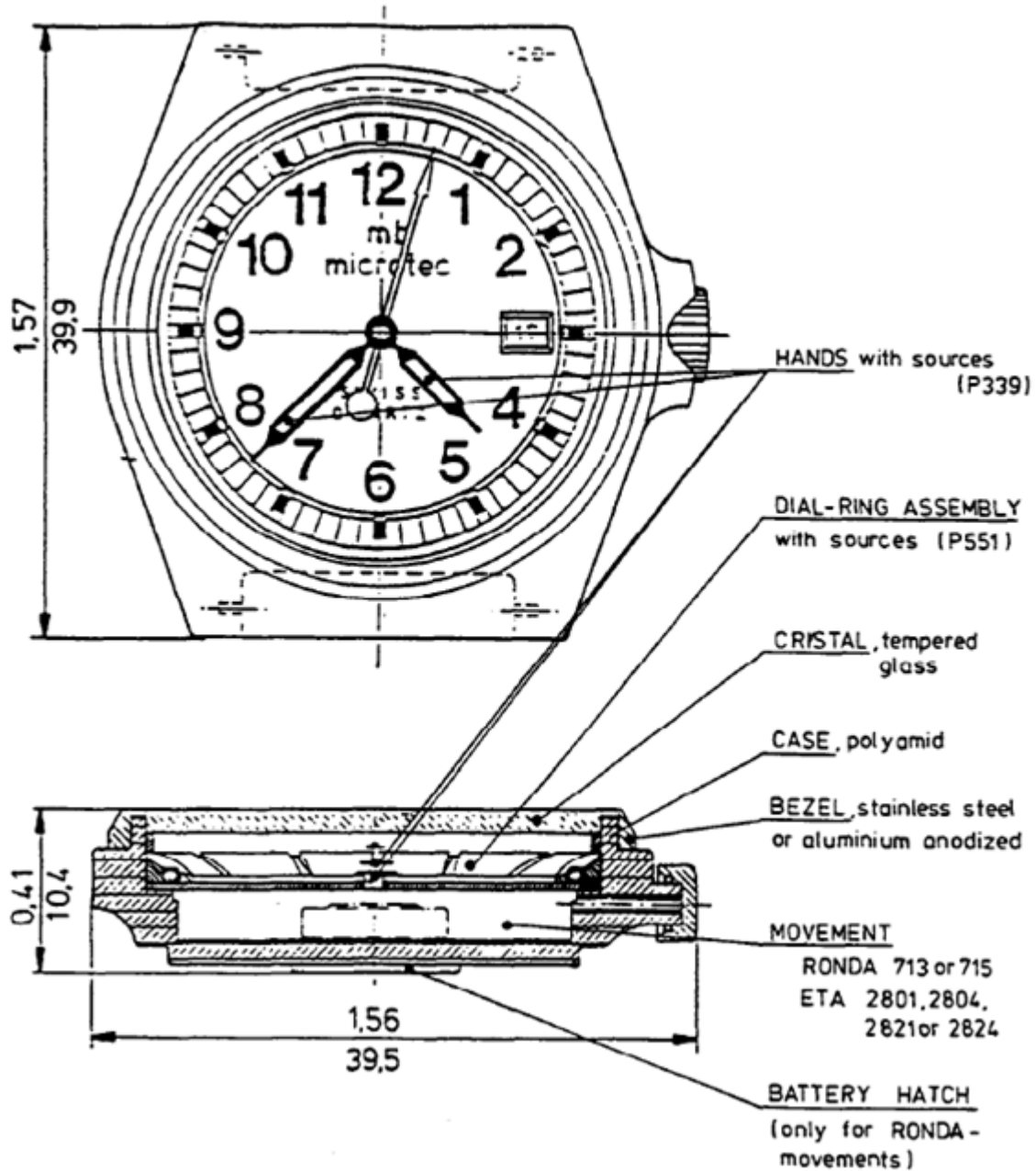
NO.: NR-0446-D-103-E DATE: December 3, 2015 ATTACHMENT 1 of 6



Former Model 375 Wrist Watch

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
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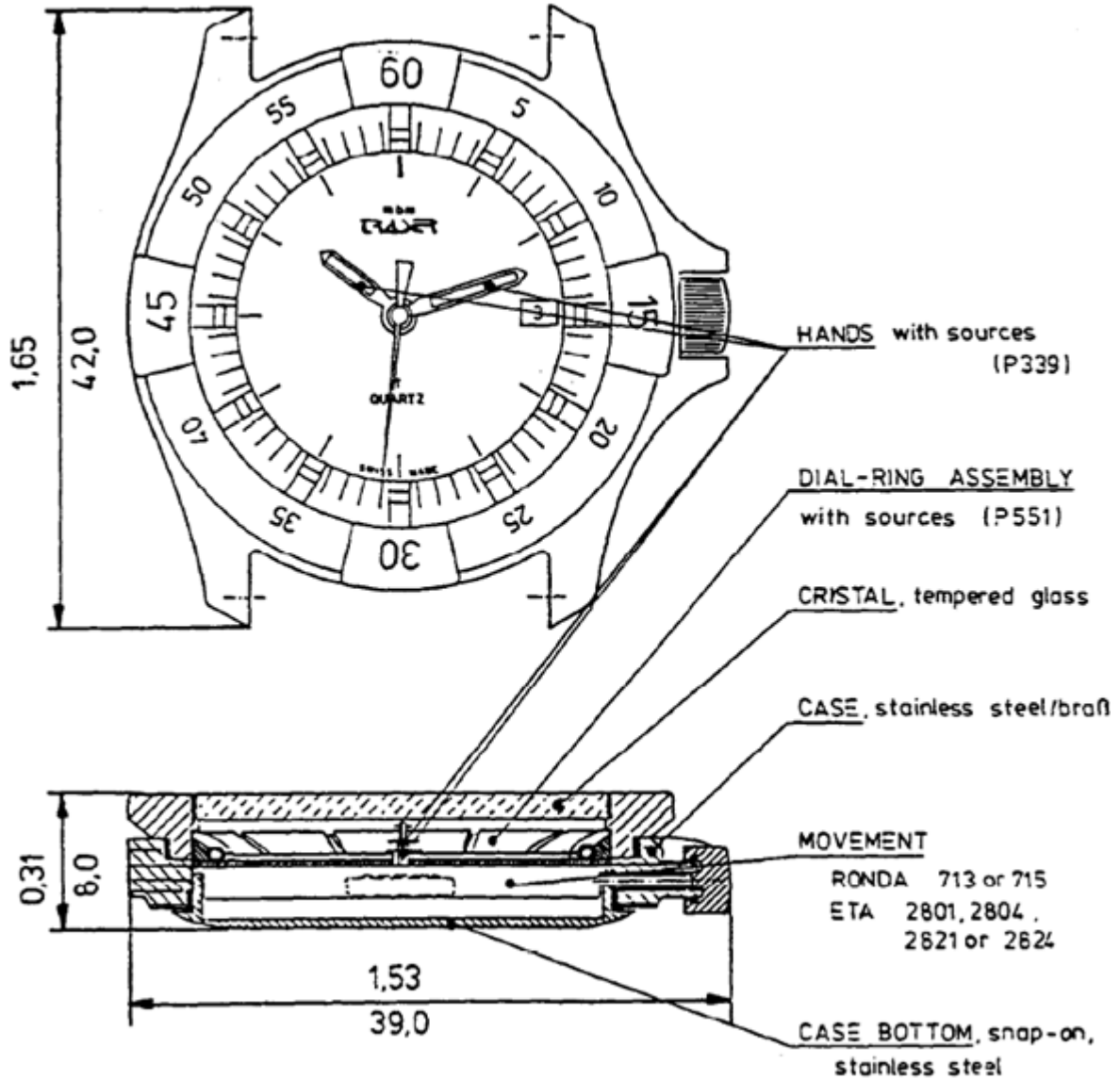
NO.: NR-0446-D-103-E DATE: December 3, 2015 ATTACHMENT 2 of 6



Former Model 550 Wrist Watch

Registry of Radioactive Sealed Sources and Devices
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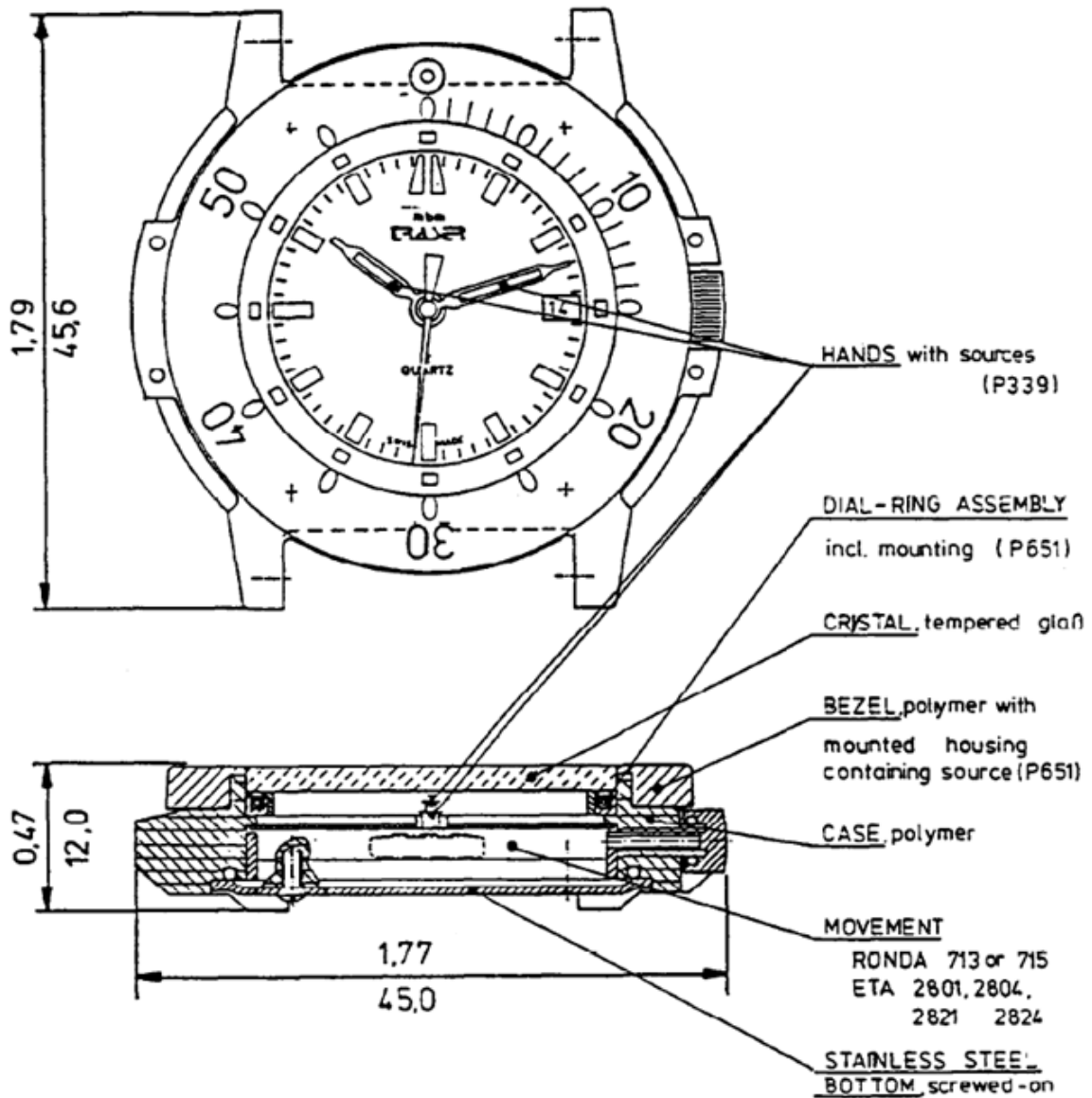
NO.: NR-0446-D-103-E DATE: December 3, 2015 ATTACHMENT 3 of 6



Former Model 600 Wrist Watch

Registry of Radioactive Sealed Sources and Devices
 Safety Evaluation of Device
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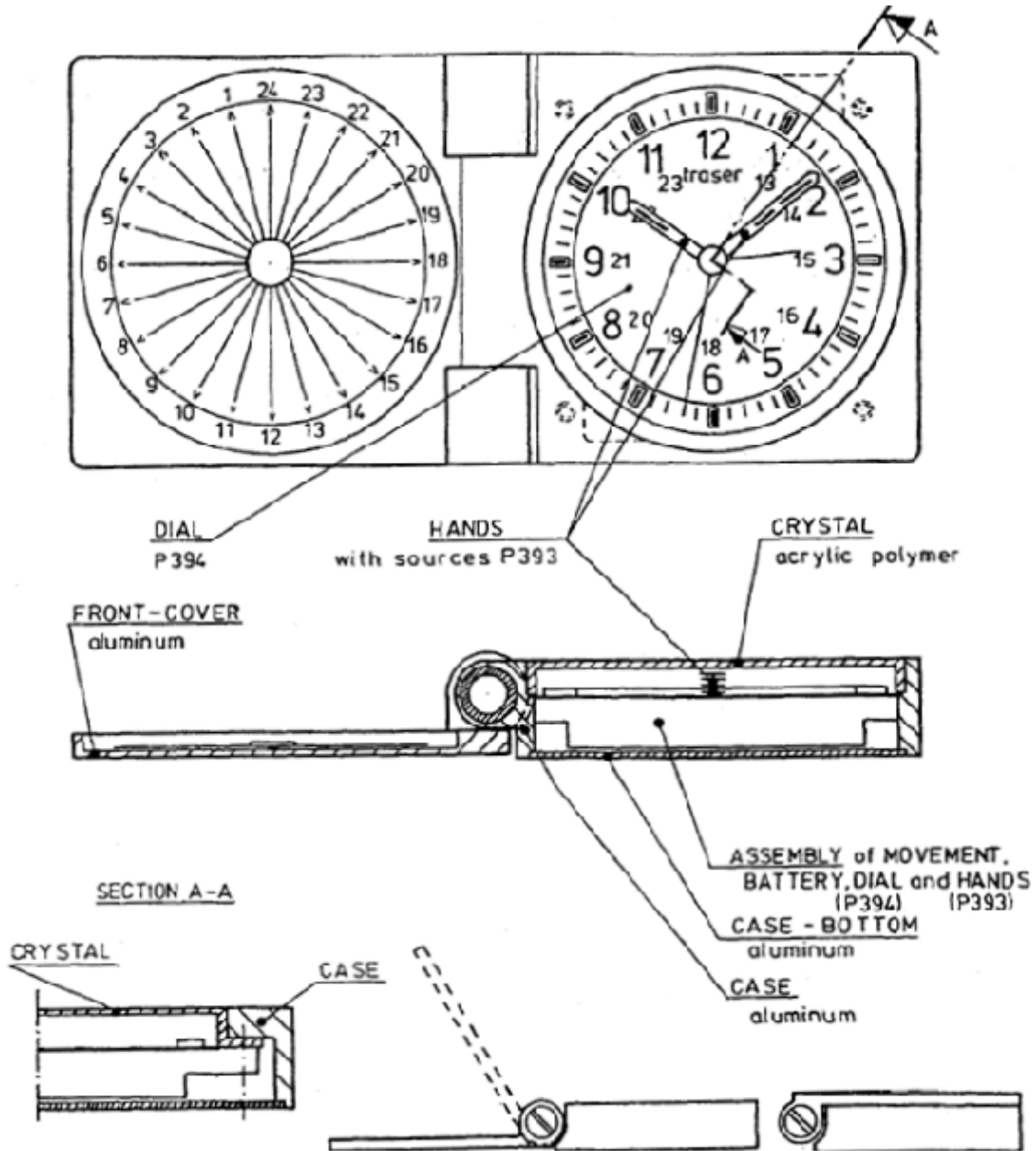
NO.: NR-0446-D-103-E DATE: December 3, 2015 ATTACHMENT 4 of 6



Former Model 650 Wrist Watch

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
(AMENDED IN ITS ENTIRETY)

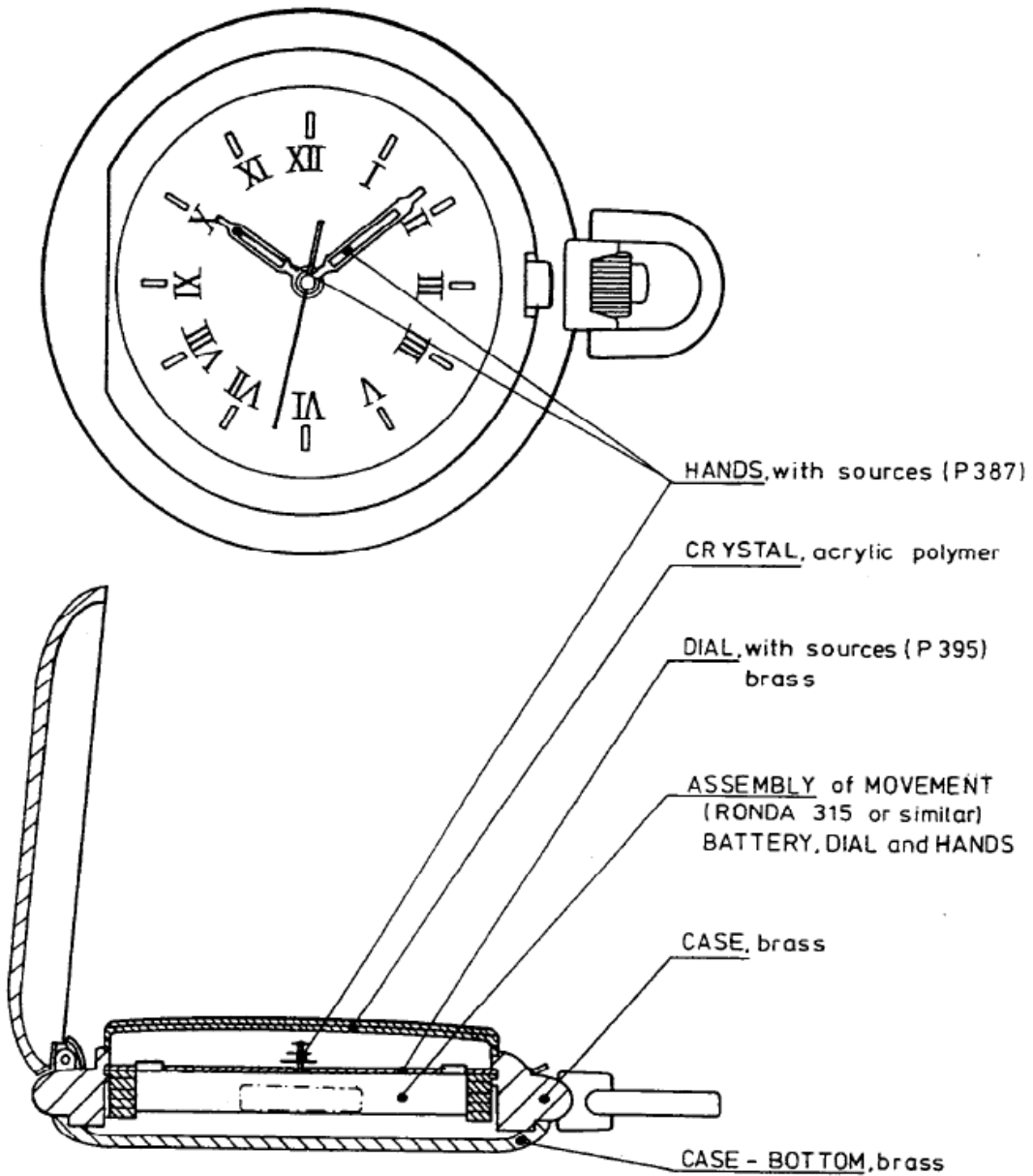
NO.: NR-0446-D-103-E DATE: December 3, 2015 ATTACHMENT 5 of 6



Model 100/4 Alarm Clock

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Device
(AMENDED IN ITS ENTIRETY)

NO.: NR-0446-D-103-E DATE: December 3, 2015 ATTACHMENT 6 of 6



Model 100/5 Pocket Watch