

December 15, 1999

Mr. U. S. Buachu USNRC Mailstop T8F27 11545 Rockville Pike North Bethesda, MD 20852

Dear Sir:

I am writing in response to our telephone conversation on December 13, 1999, which was in response to my letter dated November 12, 1999 to Mr. Strutz.

ų,

Metorex will follow your suggestion and apply for a device registration for the SUPS probe and, once the approval is received, add it to our distribution license. I agree that this approach will be less complicated than trying to research the history and reconstruct the sequence of events which apparently lead to the SUPS being dropped from the registration. Metorex will proceed as quickly as possible to complete this application and I expect that we will be able to have the submission completed by January 15, 2000.

In response to your request for a list of the probes shipped, we have reviewed the files here and prepared the attached list of probes for which records exist and believe that this is a near complete list. However, this probe has been manufactured since before Metorex existed and it is possible that there are some units in the field for which we have no records.

If you have any further questions, please feel free to contact me at (609) 406-9000 x 122 or e-mail at <u>John Patterson@MetorexUSA.com</u>.

Sincerely,

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John I.H. Patterson, Ph.D. President

JIHP/jlr Enclosure

ATTACHMENT 2

METOREX INC.

Princeton Crossroads Corporate Center • 250 Phillips Boulevard • Ewing, New Jersey 08618 • 1-609-406-9000 • Fax 1-609-530-9055

		ATTACHMENT 3			
	SUMN	MARY DATA			
Name and Complete Mailing Address of the Applicant: Metorex Inc. Princeton Crossroads Corporate Center 250 Phillips Blvd., Ste. 250 Ewing, NJ 08618		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: John I.H. Patterson, R.S.O. / President (609) 406-9000, ext. 122			
The	Applicant is (check one):	If the Applicant Is Not the Manufacturer, Provide the Name and			
	Custom User	Complete Mailing Address of the Manufacturer: Metorex International OY			
	Manufacturer	Nihtisillankuja 5 P.O. Box 85 FIN-02631 ESPOO			
XX	Distributor				
	Manufacturer and Distributor	Finland			
	e Applicant Is a Custom User, Provide the Name and plete Mailing Address of the Distributor: N/A	Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: N/A			
Mod	el Number: SUPS 0484 & SUPS 2476	Principal Use Code (see Appendix F): U			
Nam	e Used by the Industry to Identify the Product (e.g.,	For Use by:			
	ography Exposure Device, Teletherapy Source, bration Source, etc.):	Specific Licensees Only			
		X General Licensees Only			
	XRF Probe	Both Specific and General Licensees			
_		Persons Exempt from Licensing			
Leak	-Test Frequency:	Principal Section of the 10 CFR that Applies to the User (e.g.,			
	Periodic Leak-Testing is Not Required	General Licensees under 10 CFR 31.5): 10CFR31.5			
X	6 Months	Radionuclides and Maximum Activities (including loading			
	Attached is justification for a leak test frequency of greater than 6 months	tolerance): Am-241 30mCi; Cm-244 60mCi			

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

	ficer — Typed Name and Title Patterson Ph.D., R.S.O./President	
Signature:	Jeh glas	Date: 1/14/00
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NUREG - 1556, Vol. 3

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Registration Certificate Holder: Metorex Inc.	<u> </u>	· · · · · · · · · · · · · · · · · · ·
Model: SUPS 0484 & SUPS 2476		
DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION		
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	OK	Only different shutter activation
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	OK	
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security	OK	
Is source ANSI classification sufficient (from ANSI N542-1977): Radiography - Unprotected	OK	
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	OK	
On-Off indicators (description, qty., location)	OK	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	OK	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)		
Shielding efficiency and integrity		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		

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CHECKLIST

Registration Certificate Holder:

Metorex Inc.

Model: SUPS 0484 & SUPS 2476

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DESCRIPTION	OK/DEF	COMMENTS				
LABELING						
Copy of label	ОК					
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	. Tr.				
Permanent attachment and location(s) - visible to users?	OK					
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	OK					
CONDITIONS OF USE						
Expected working life of the source/device (years, operations)	5-10					
Actions to be taken when product reaches end of its working life.	ОК	Return to manufacturer				
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK					
How the device will be used	OK					
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	ОК					
PROTOTYPE TESTING/HISTORICAL USE						
Tests methods and conditions (for source and device)	OK	· · · · · · · · · · · · · · · · · · ·				
Tests results	OK					
Years of use (incidents, failures, etc.)	ОК					
Similarities to other sources/devices if they are used as basis.	OK					
RADIATION PROFILES						
Survey instrument used (type, window thickness, sensitivity, etc.)	OK					
Conditions: including environments, scatter (product in beam), and use of guards and shields	ОК					
Distance from source/surface (per ANSI 538-1979)	OK					
Shutter Open and Closed/Source Shielded	OK					
Verify radiation surveys for γ radiation meet inv ² law.	OK					
Verify radiation surveys for non- γ radiation have not been calculated using inv ² law.						

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CHECKL	IST	
Registration Certificate Holder: Metorex Inc.		
Model: SUPS 0484 & SUPS 2476		
DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		······································
Materials, subassemblies, services	ОК	
Assembly methods (screws, welding, etc.)		· · · · · · · · · · · · · · · · · · ·
Dimensions and tolerances		······································
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to Regulatory Guide 6.9		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing	ОК	
Inherent shielding, inaccessibility		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	·	
Mounting integrity		<u> </u>
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	ОК	
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	ОК	
Transportation documents	OK	· · · · · · · · · · · · · · · · · · ·
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	ОК	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	OK	

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January 14, 2000

X-MET PROBE SUPS 0484 & SUPS 2476

1. PRACTICAL SAFETY ASPECTS IN THE USE OF THE SUPS PROBE

The SUPS probe contains one radiation source. The probe must be used by only a person who have been trained to operate the probe so that they do not cause radiation danger to themselves or to the nearby people.

When the probe is not used it must be stored in a safe place where no unauthorised person can handle it.

The radiation source must changed only by authorised persons.

The labels on the probe must not be removed or covered.

If there is any doubt that the shutter has remained open it is necessary to take a look at the shutter using a mirror. If the shutter has not fully covered the source the measuring window must be covered by at least 1 mm. thick lead plate and the probe must be sent for repair.

2. GENERAL DESCRIPTION OF THE SUPS PROBE

X-Met is an X-ray fluorescence analyser where the excitation source is either a radionuclide or an X-ray tube. SUPS is one of the radionuclide excited probes. Photographs 1 and 2 (on pages 9,10) and Figure 1 (p12) show the probe. These probes are meant only for surface measurements. The probe has one radioactive source that is located in the middle of the bottom part of the probe.

In the SUPS 0484 probe, pushing the probe against the sample opens the shutter. This causes the button on the bottom of the to move the shutter and expose the source. The measurement can not start unless the shutter is fully open. This action engages a microswitch which starts the measurement. In the SUPS 2476 probe pressing the probe against the sample releases the shutter interlock. Pressing the button on the handle opens the shutter electronically and starts the measurement. The measurement is stopped either by the clock after the pre-set time has elapsed or when the probe is lifted from the sample enough that the shutter starts to close. Lifting the probe from the sample makes the retracting spring turn the shutter to the closed position. The measurement result is shown in the display of the main unit.

To keep the spectral stability good a reference sample that is glued to the shutter is measured when the shutter is closed. The position of the shutter/reference is sensed by microswitches.

A light in the handle indicates by green color that the shutter is closed and the probe is not ready for the measurement and by red color that the shutter is open and the measurement is in progress. If this light turns green during the measurement due to lifting of the probe, the measurement is interrupted and must be started anew after adjusting the position of the probe properly. If the light remains red when the probe is lifted, the shutter is not completely closed and corrective action is required.

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s/N-

When not in use the probe is stored on a the calibration base having a properly positioned hole for the push button of the probe to prevent accidental opening of the shutter.

3. RADIATION SOURCES

The sources for these probe are manufactured by Amersham International plc (UK). The Am-241 source used is a 30 mCi Type AMC.D2 capsule type X.10/2 which achieved a classification of C44344 based on the ANSI guide N542-1977. The Cm-244 source used is a 60 mCi Type CLCL capsule X.130/7 which achieved a classification of C64545. Attached are the registrations for the AMC.D2 Americium source starting on page 35 and the CLCL Curium Source starting on page 39. The minimum requirement set for the radiation source of an XRF analyzer is C33222 and thus all the above sources fulfill this requirement.

The radiation profile of the SUPS probe are enclosed beginning on page 43.

4. WARNING LABELS

The probe is equipped with warning label(s) bearing the radiation symbol and giving the name of the nuclide of the source, its activity and the date of the measurement of the activity (see Label 2, p11) which is placed on the right side of the probe (shown in photograph 1 without the labels). In addition the label has the text required for a Generally Licensed device (see Label 1, p11) which is placed on the top of the probe (directly below the handle). The probe is also marked with the type of the equipment and the name of the manufacturer.

5. CONSTRUCTION OF THE PROBE

5.1 General construction

Figure 1 (p12) shows in 3 projections of the probe. It is a simple box having a handle and on the bottom a round plate protruding from the box. In this round part there is a window covered with a Mylar film and somewhat off center, a push button that operates the shutter located behind the window. Behind the shutter there is the radiation source just in front of the detector window. The detector is a cylindrical proportional counter. Above these parts, in a separate compartment, are the electronic circuits necessary for the probe. The main analyzer (not shown here) contains most electronics such as the power supplies and data handling electronics. Figure 1A (p13) shows the Calibration Base for the unit. This base is machined so that the probe easily fits into the base and aligns with the center hole. For calibration, a standard is placed in the center well and the probe is places so that the shutter opens. For storage, the probe should be placed the opposite direction on the plate where the shutter button will fit into the hole to prevent the shutter from opening.

5.2 Constructional details

Figures 2-4 (p 14-16) present the two (2) covers and the frame between them. Almost all the components are fixed to this frame. The electronic circuits attach to one side of the frame and the detector and the other components directly related to radiation to the other side. The detector is fixed with part 16 in Figure 1 (p12). The radiation source (part 20) is fixed first to the source holder with a seger ring (part 18) and the source holder (Figure 16, p 30) is attached with two (2) screws (part 27) to the same part that holds the detector (part 16). On top of this comes the measurement base shown in Figure 5 (p17). When Cover 1 is fixed with four (4) screws (part 24 in figure 1) to the frame the radiation is limited to the compartment between these two parts.

The measurement base and its components are shown in Figures 5-15 (on p 17-29). The aluminium mounting base (Figure 6, p18) is lined on the inside with lead for radiation shielding and those parts of lead that could give disturbing fluorescence radiation to the detector are covered with thin iron and aluminium plates. The shutter comes as close to the cover and correspondingly the source as close to the shutter as possible. Microswitches S1 and S2 sense the position of the shutter. The window of the probe is covered with a mylar foil to prevent dust and humidity from getting into the probe.

Figure 12 (p 24) shows the shutter mechanism for the SUPS 0484 probe. Figures 12A and 12B (p 25,26) are photographs of a shutter assembly to illustrate the motion. When the probe is pushed against the sample part 15 in the upper drawing of Figure 12 moves upwards and the top of the long rod (part 14) moves to the left, this causes the shutter to open. The top end of the rod pushes the oblique (see the lower drawing) edge belonging to plate 2 making the plate turn to the left. Both the lever and the plate are spring-loaded and they will close the shutter when the push button is released. The radiation is stopped by parts shown in Figures 13-15 (p 27-29). These parts are glued on top of each other to the area 12 in Figure 12 (p24).

Figure 20 (p 34) illustrates the construction of the SUPS 2476 probe. The main assembly, the detector and source are identical to the SUPS 0484 probe. The compisition of the shutter is also the same as in the SUPS 0484 probe. The shutter activation mechanism is the only difference. In the SUPS 2476 probe, the shutter interlock pin

releases the safety interlock. This allows the rotary solenoid to rotate the shutter assembly when the button on the handle is pressed. The shutter is spring loaded so that a failure of the solenoid will immediately close the shutter. If the probe is lifted during operation, the safety interlock interrupts the power to the shutter, thus closing the shutter. In this probe the light will glow green only when the shutter is closed completely.

Figures 17-19 (p 31-33) show the steel plates that cover the electronic circuits and at the same time improve the radiation shielding upwards. Cover 2 (Figure 4, p 16) closes the whole box.

6. CONDITIONS OF USE

The SUPS probe is normally used in indoor settings, however, occasionally it is used as a portable field device. It is operated in conjunction with an electronic analyser such as the Metorex 880 or the earlier 840. Thus, the environment will in general be quite mild. The unit may be operated between 0°C and +60°C. It may be stored at temperatures from -40° C and +85°C. The major mechanical stress will be vibration during shipment and possible transport by the user prior to use.

7. PROTOTYPE TESTING

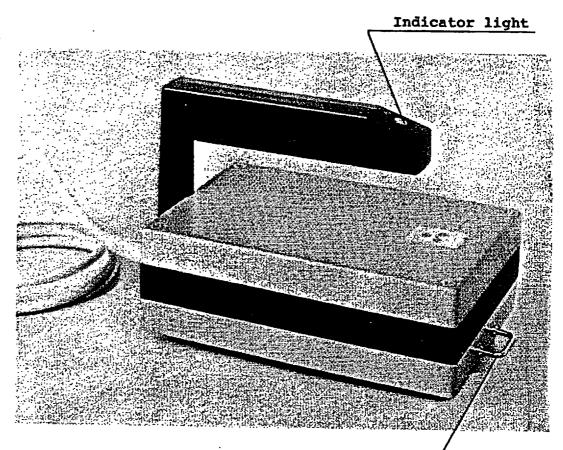
A total of approximately 11 SUPS (mostly of the 0484 probe) were sold in Europe in the early 1980's and 17 SUPS probes (mostly of the 2476 probes) were sold in the United States in the 1980's and 1990's. If we assume that the average useful life was 5 years (a very conservative estimate), this represents a total operational history of 140 years. There are no known cases in which the probe failed is such a way to generate radiation in excess of the values shown in the attached radiation profiles. The shutter failures that have occurred have been with the shutter jammed in the closed position.

8. QUALITY ASSURANCE

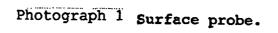
The SUPS probes are manufactured by Metorex in compliance with the ISO 9001 certification. When they are received at Metorex Inc. the unit is tested for operation, integrity of construction and assembly, accuracy of the paper documentation and analytical performance. The record (Technical Passport) of the instrument is maintained by Metorex Inc. Any deficiencies in the analyzer construction or operational performance are corrected if feasible, or the probe is returned for repair.

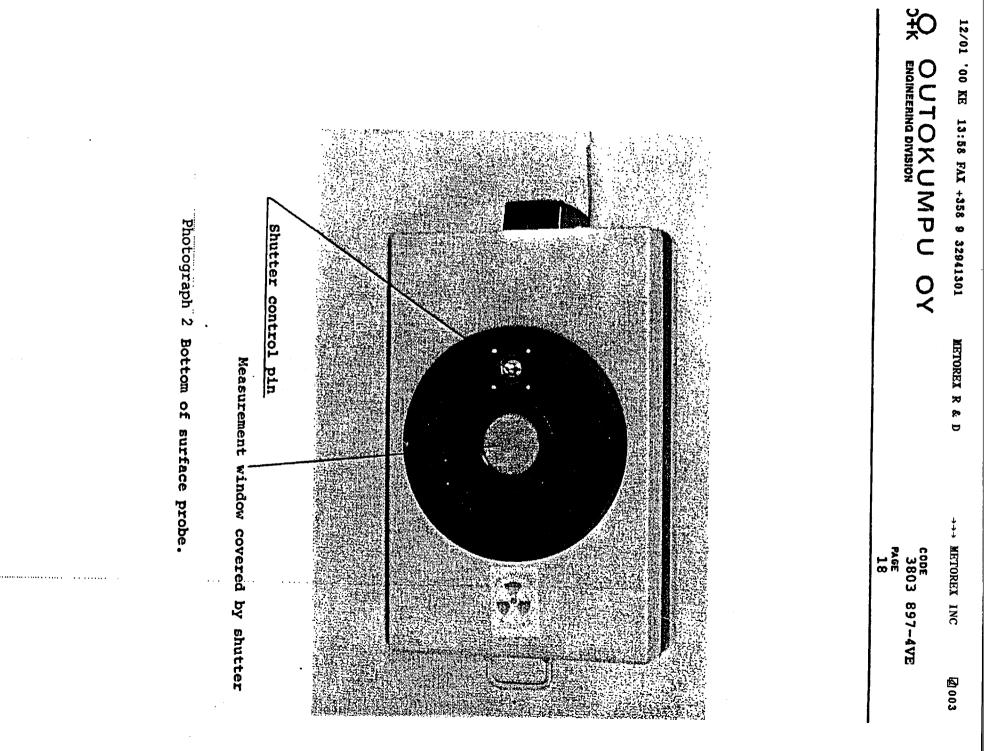
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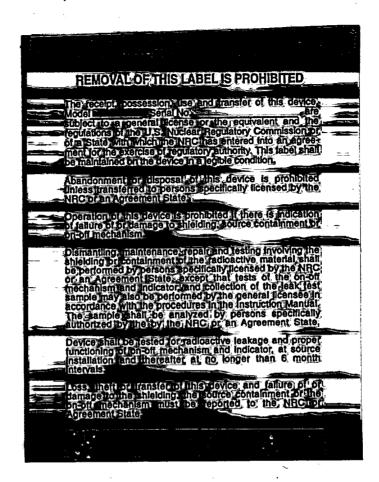
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Hook for hanging the probe on the carrying case





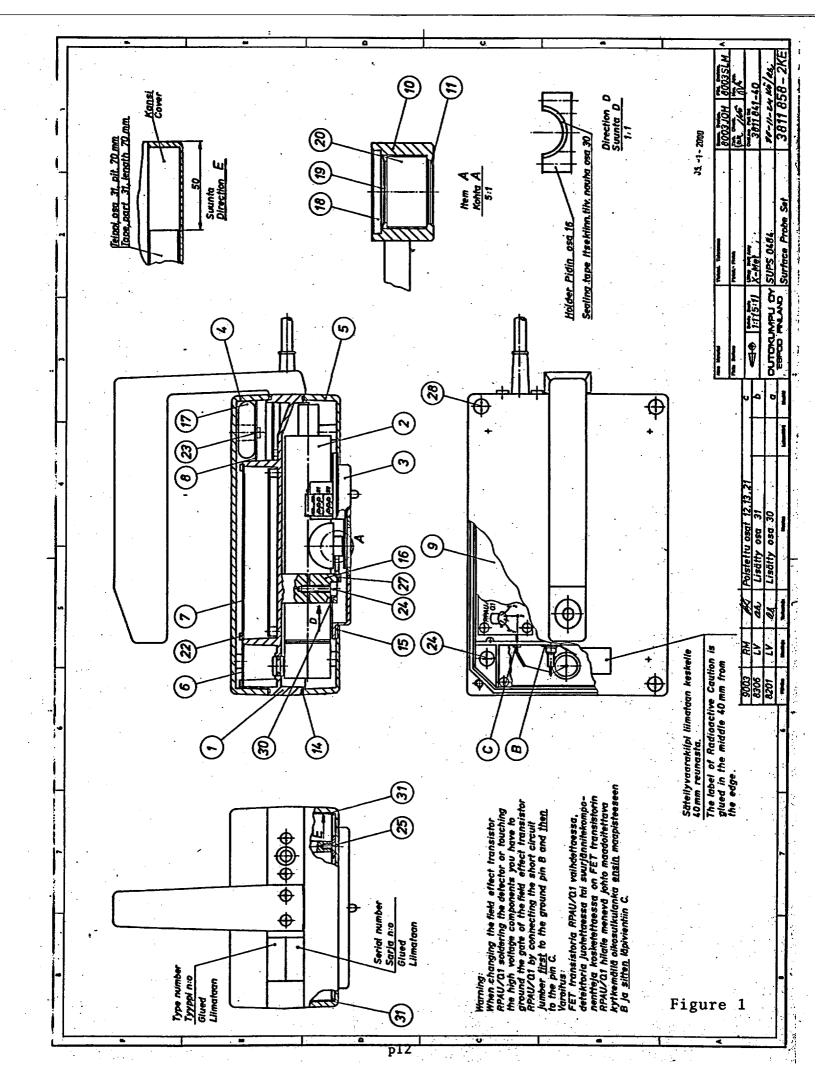


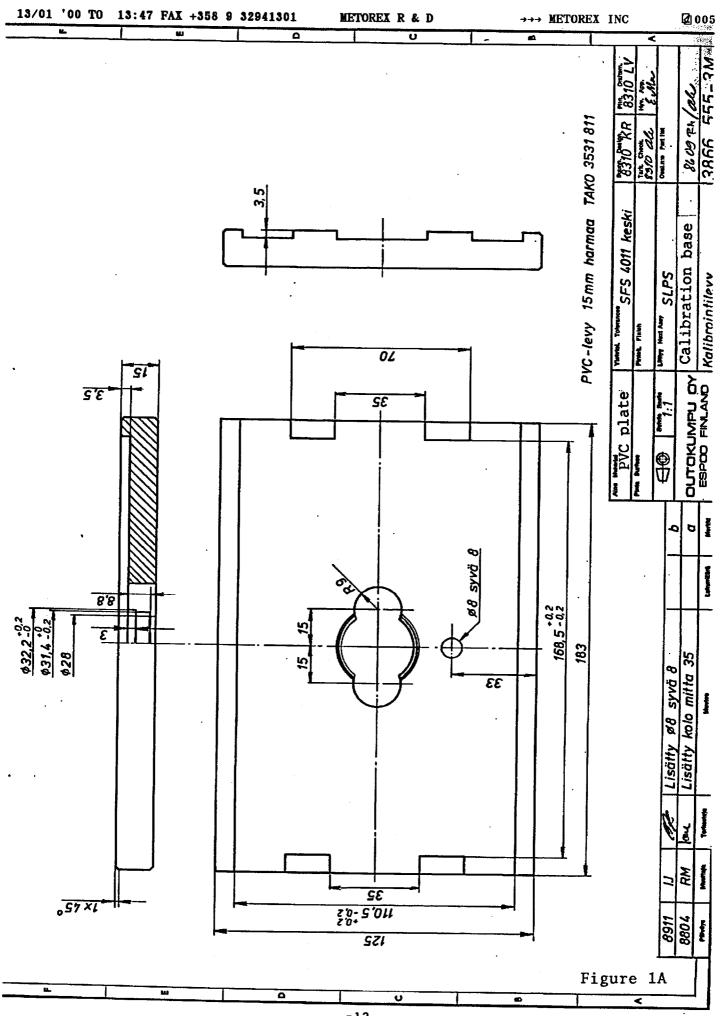
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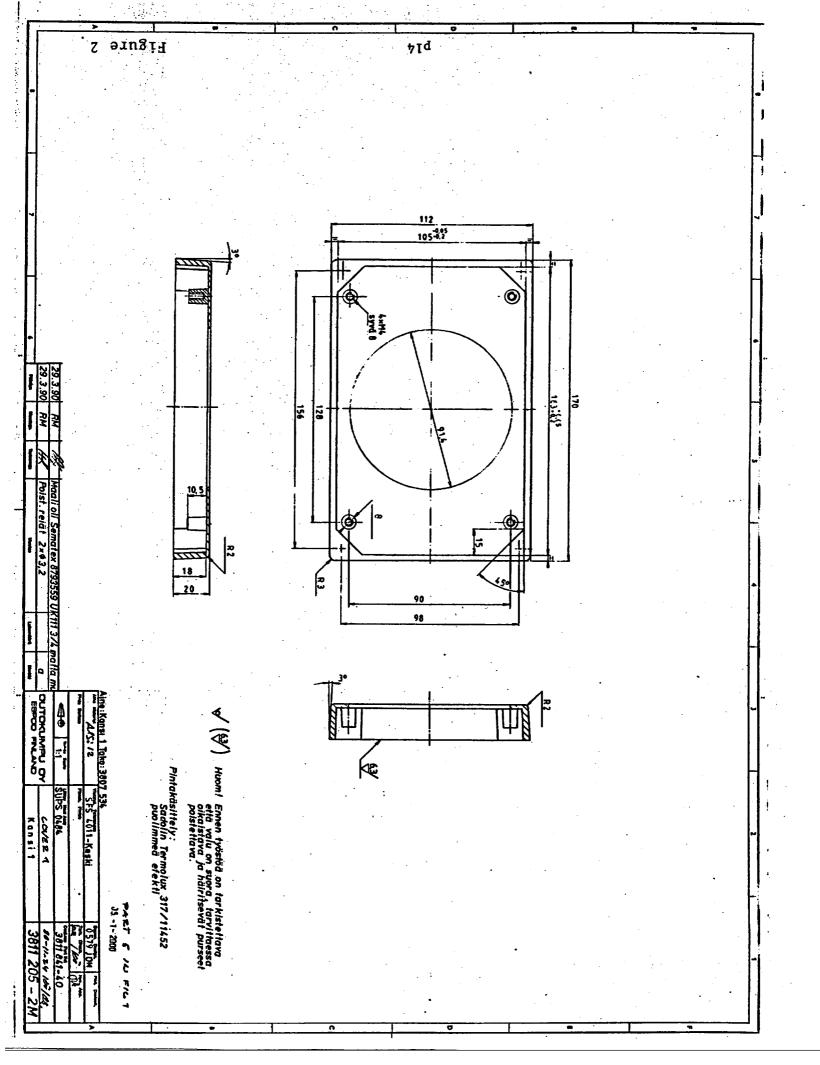
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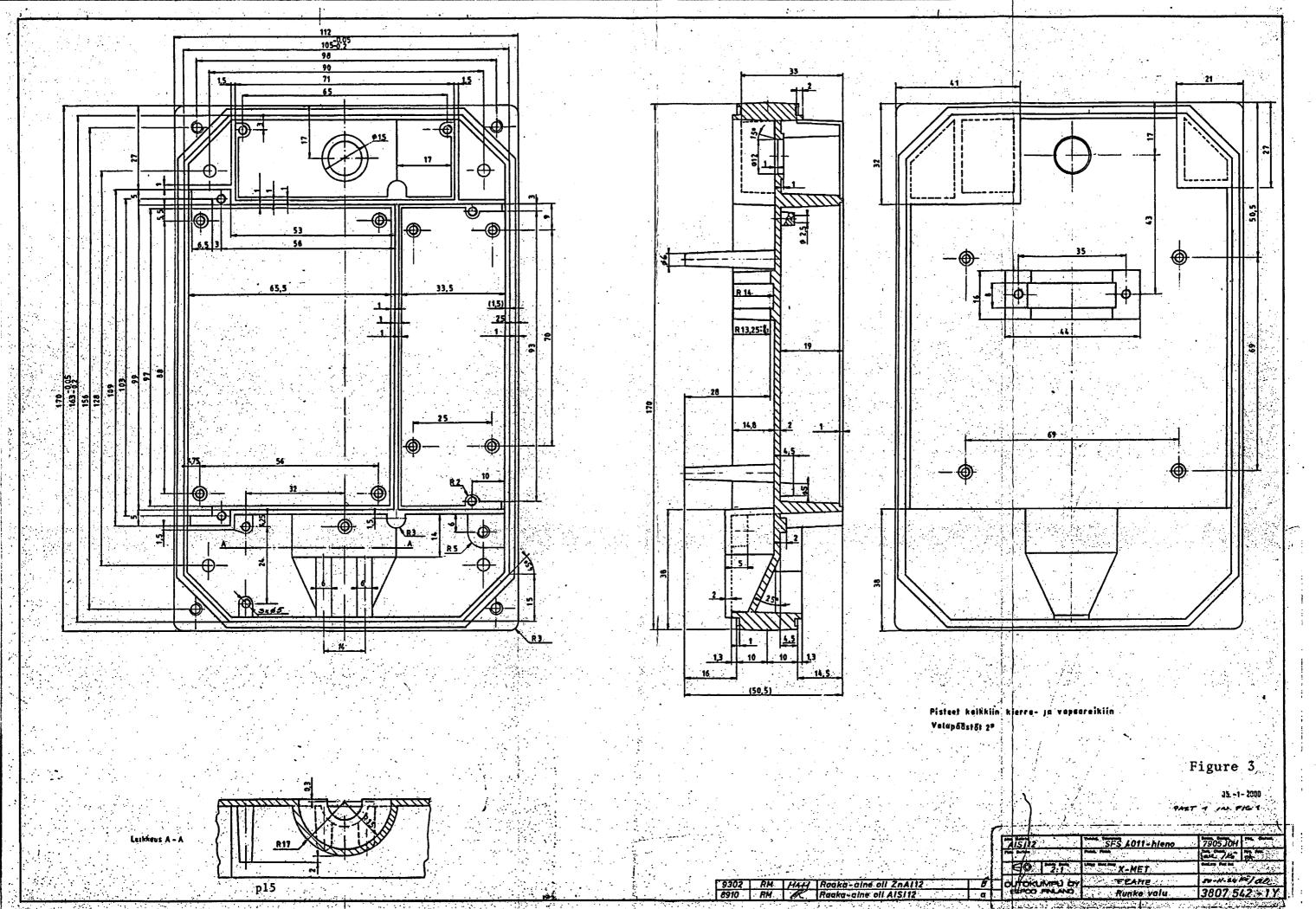
CAUTION RADIOACTIVE MATERIAL	Device Model Device S/N Isotope Isotope S/N Millicuries Date
REMOVAL OF T	HIS LABEL IS PROHIBITED
ME	TOREX INC.

Label 2

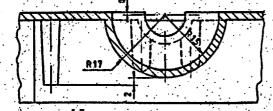


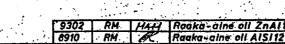


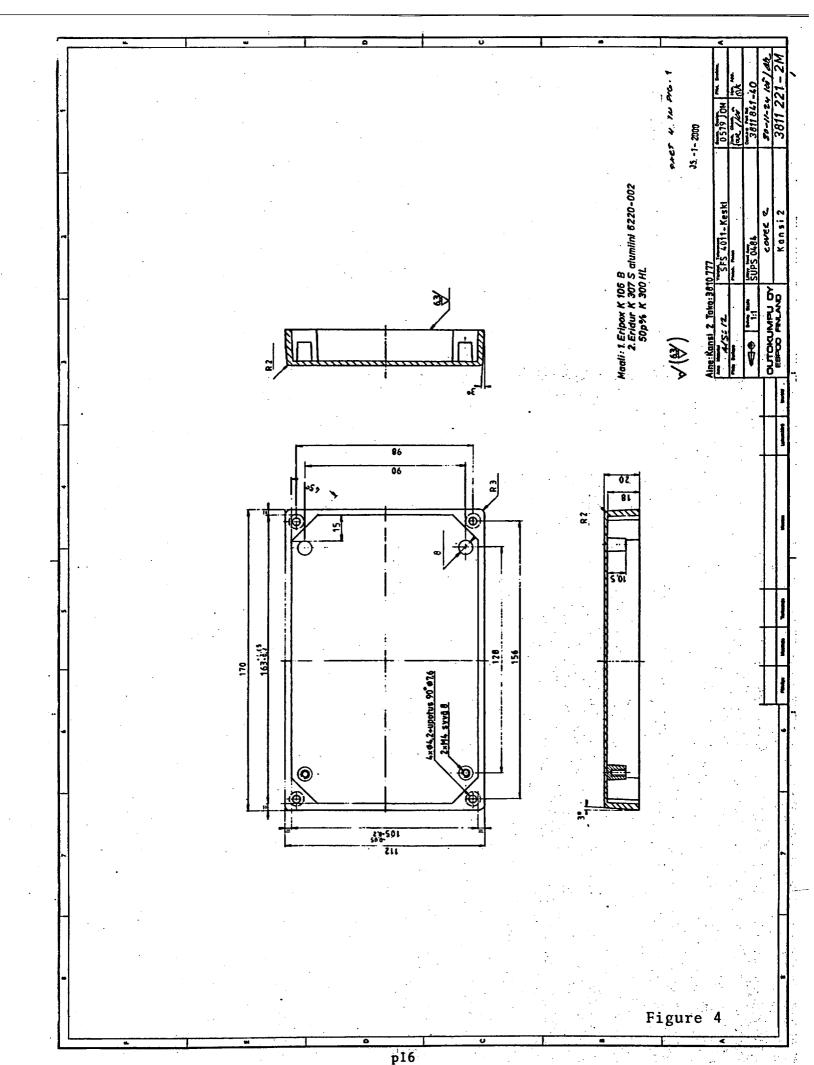




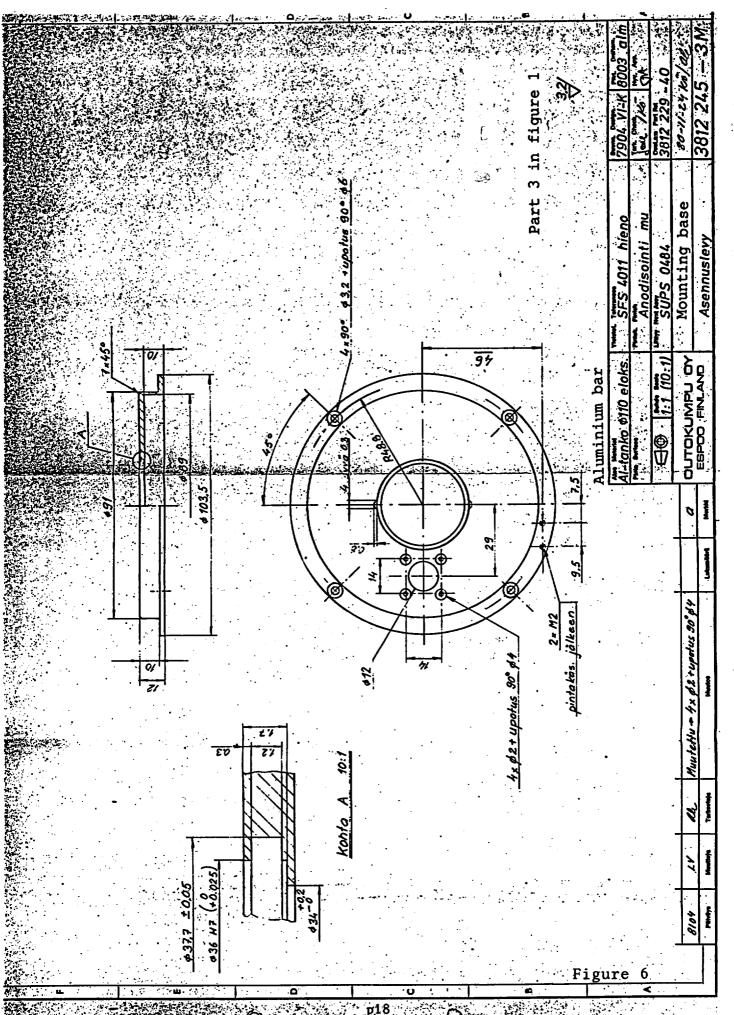


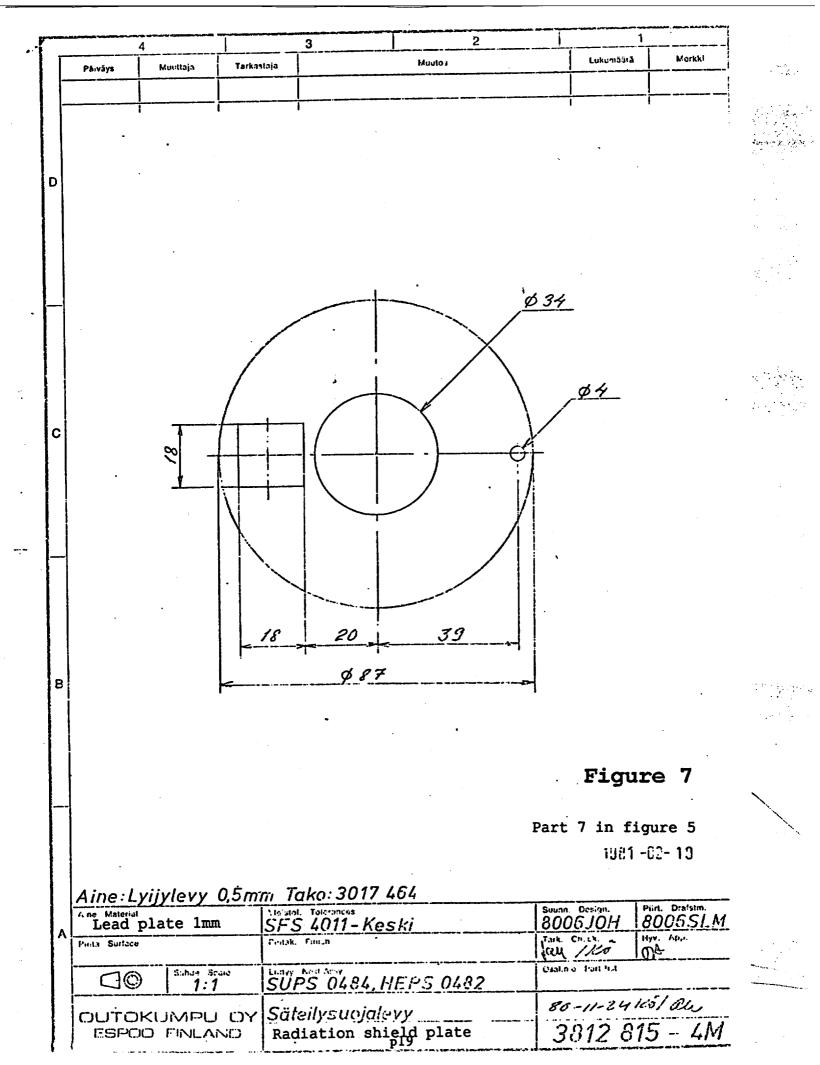






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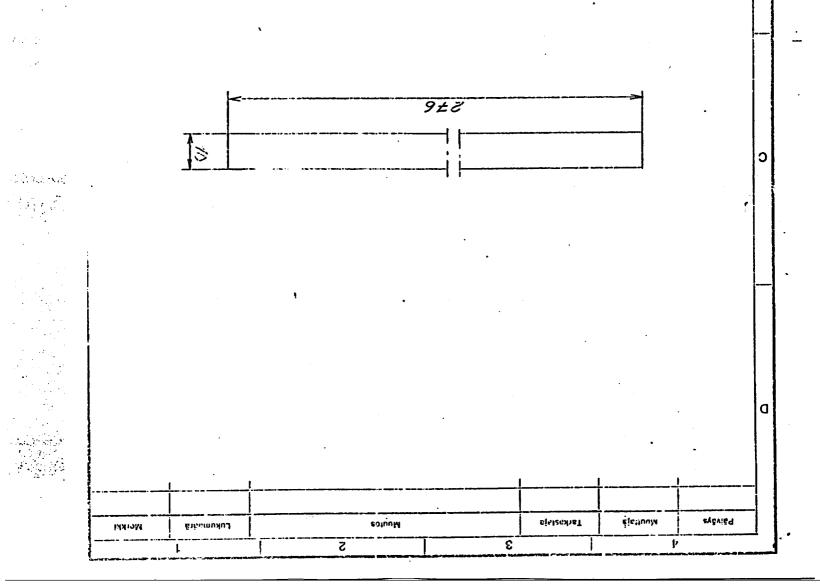
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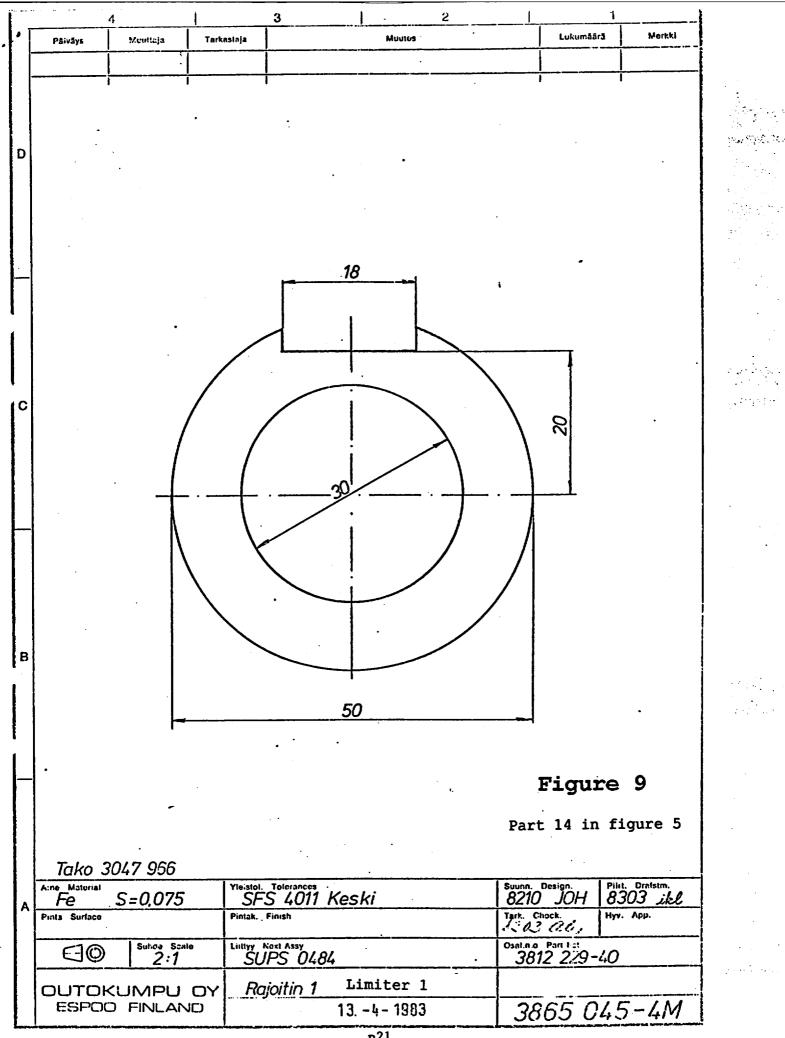
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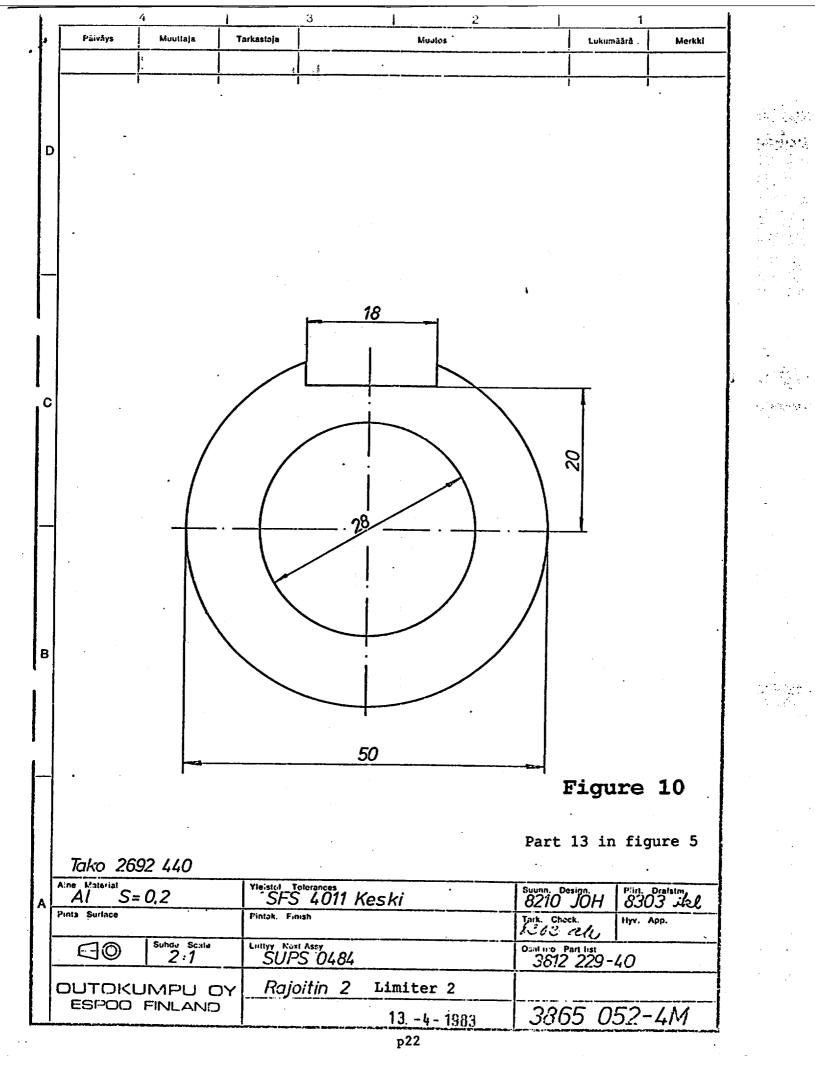
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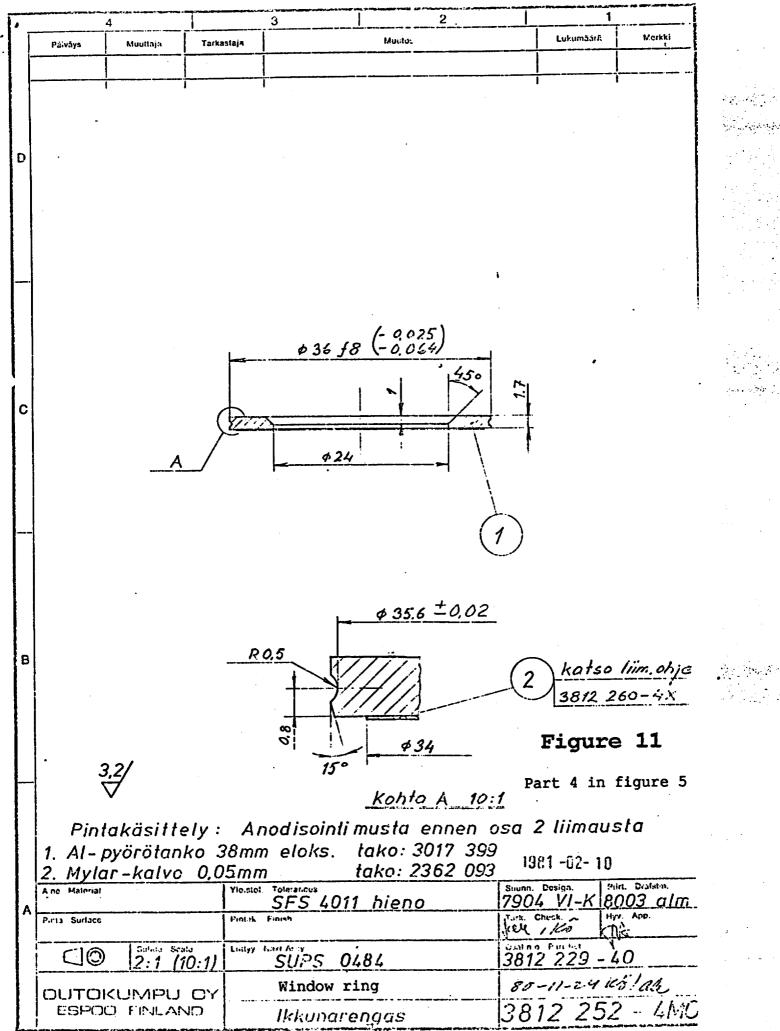
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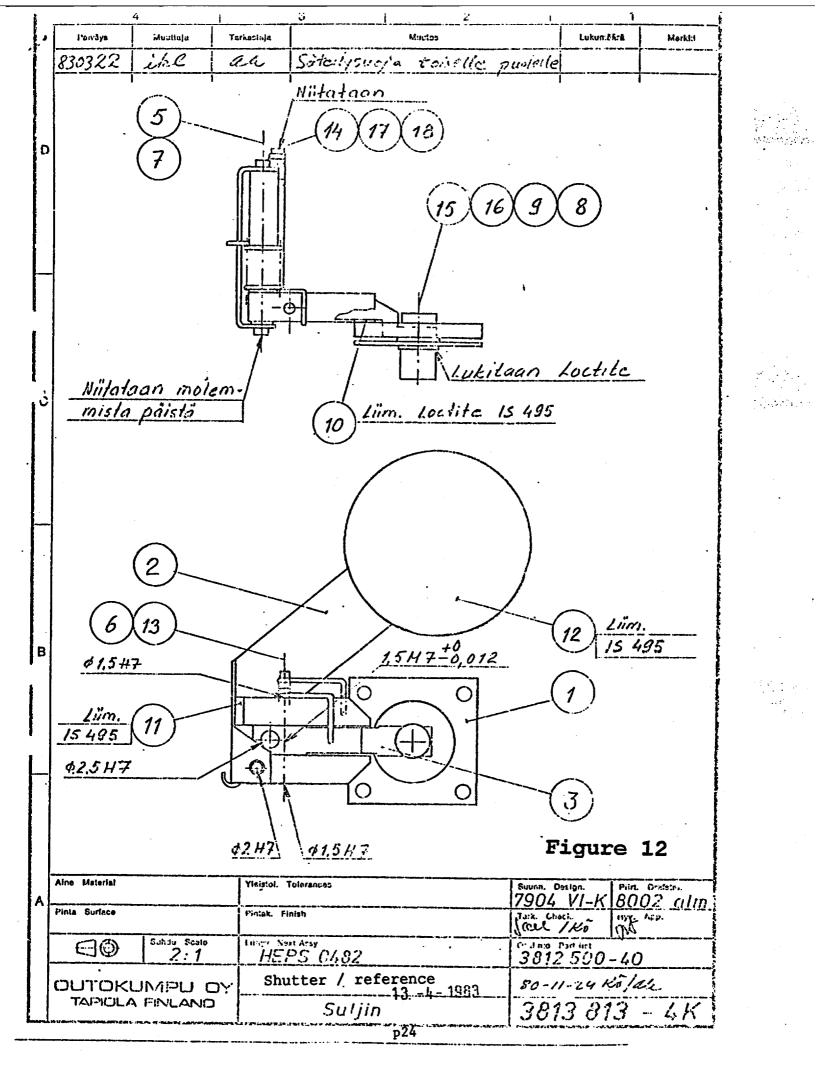




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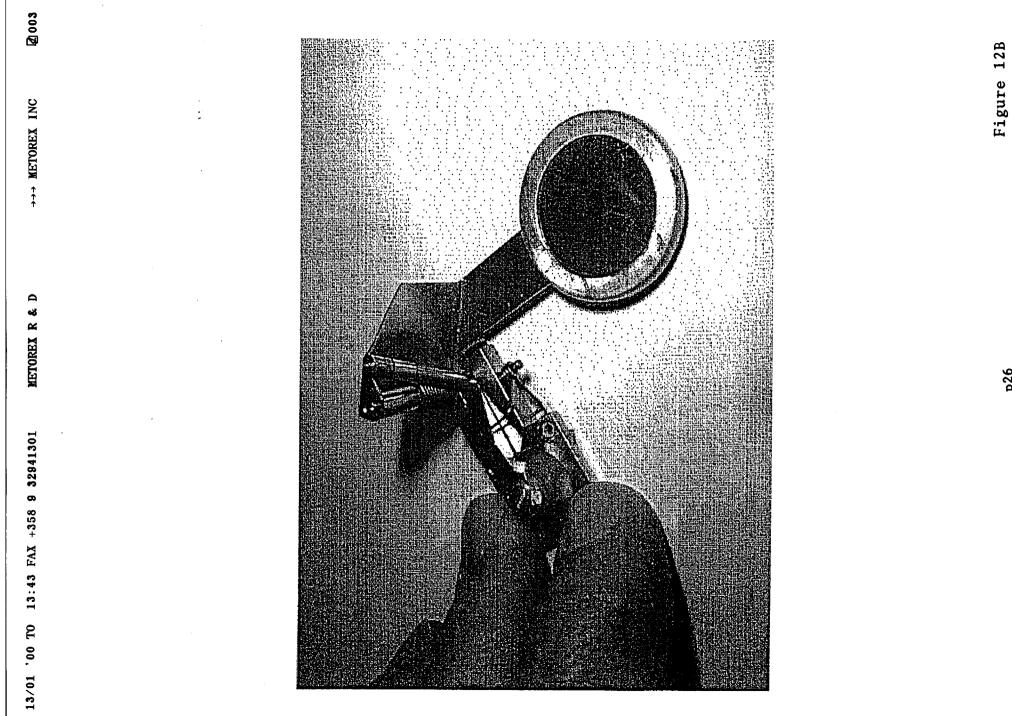


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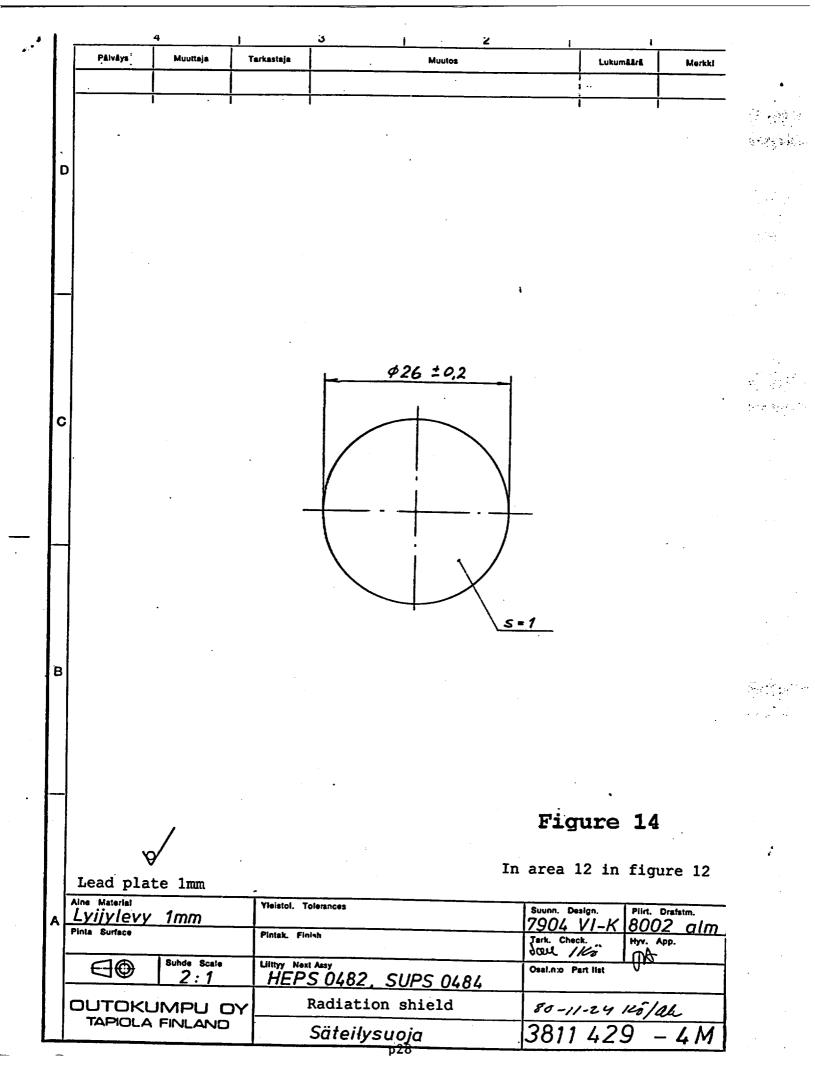
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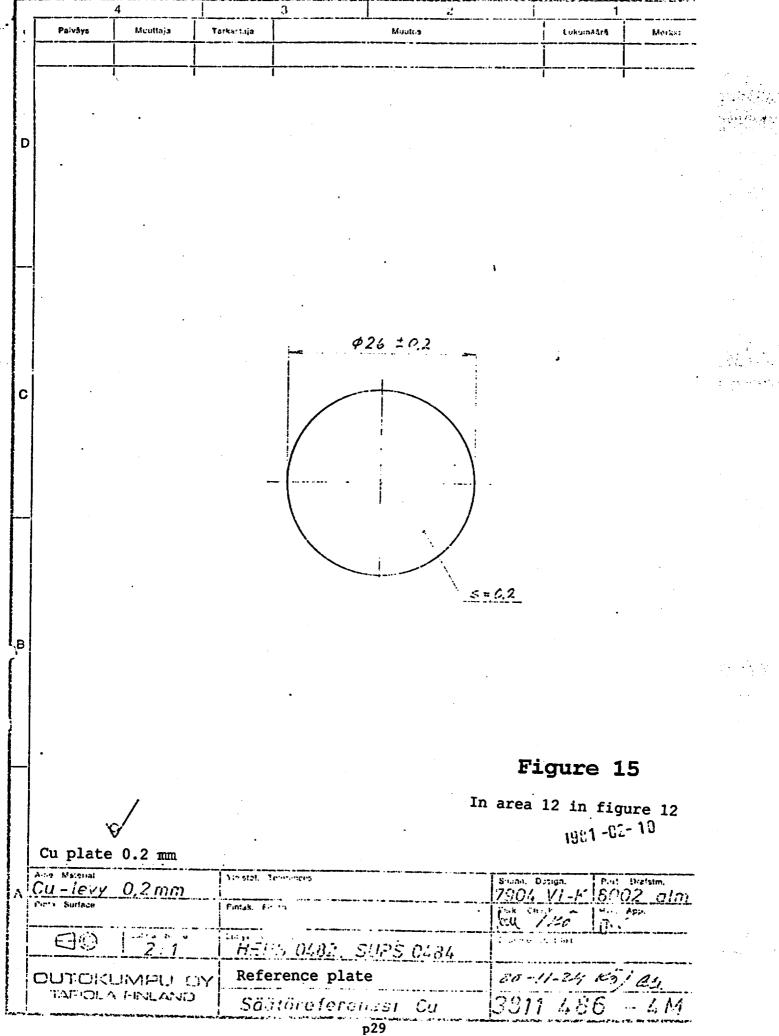
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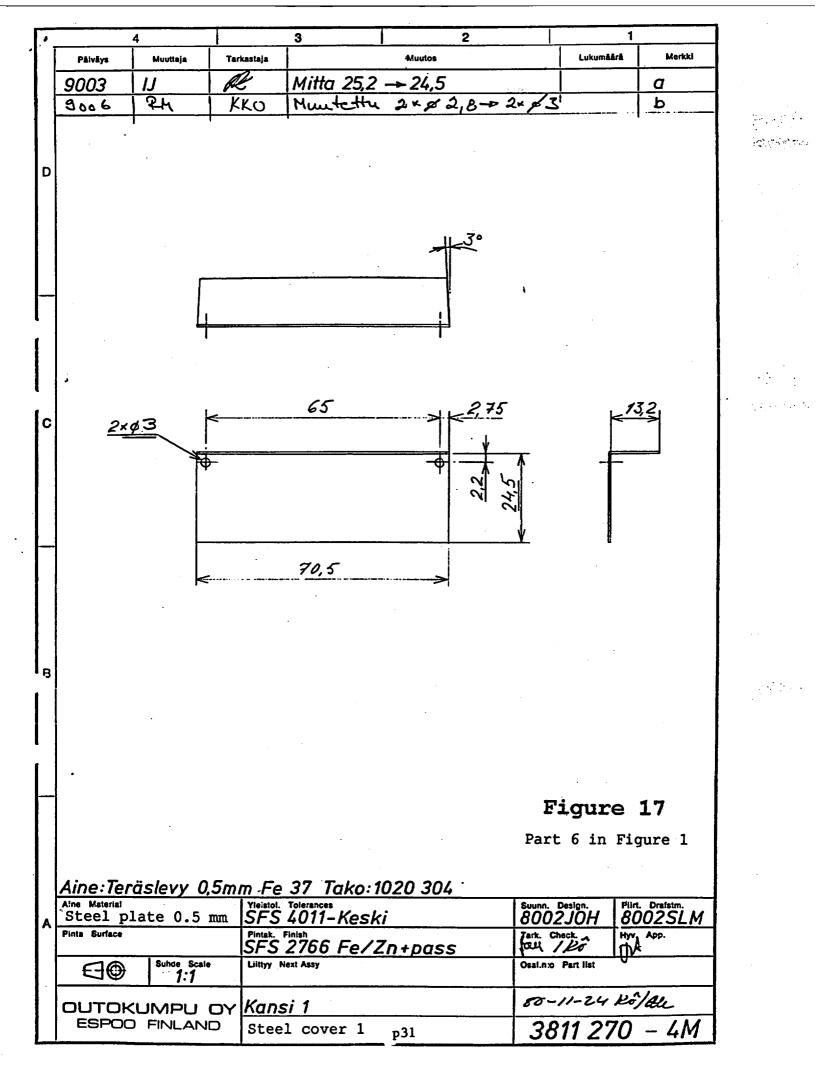
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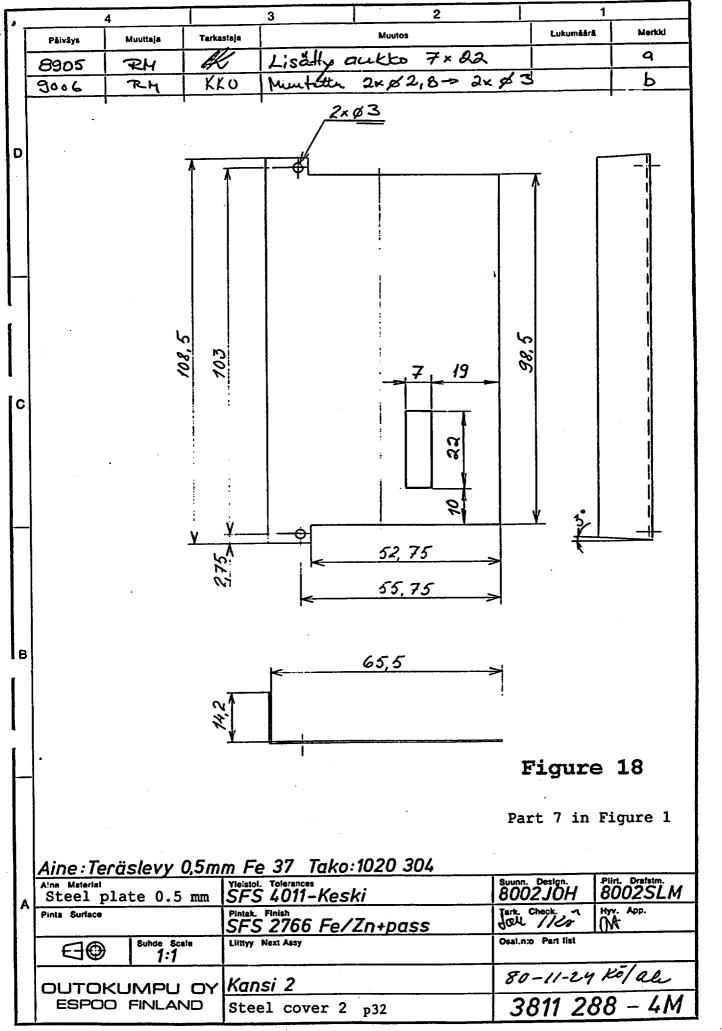
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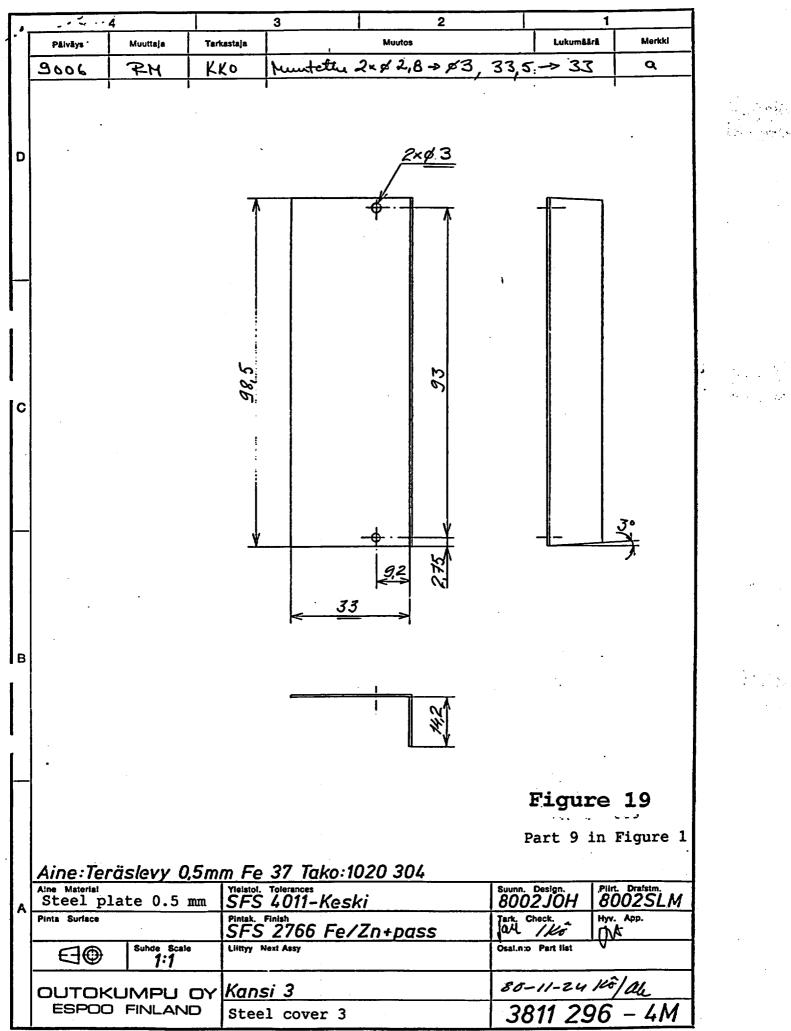
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