Federal Office for Radiation Protection

Approval Certificate

D/2012/B(U)-85 (Rev. 14)

for a type B(U) package for radioactive materials

In response to the application dated 08.04.2013 by the company NTP Radioisotopes (Europe) S. A., Fleurus, Belgium, (file number: JL-130408_BFS_TI), the transport and working container with the manufacturer designation GammaMat TI-F is approved as a type B(U) package for radioactive materials according to the following regulations for road, rail, ocean, inland waterway, and air transportation carriers:

Regulations for the Safe Transport of Radioactive Material, 2009 Edition, International Atomic Energy Agency (IAEA), No. TS-R-1, § 817,

European accord dated September 30, 1957 on the international transportation of dangerous goods by road (ADR) (Federal Law Gazette 1969 II pg. 1489), attachments A and B in the version published on November 25, 2010 (Federal Law Gazette 2010 II pg. 1412), last modified by way of the 23rd ADR amendment dated March 08, 2013 (Federal Law Gazette 2013 II pg. 309).

Ordinance on the international carriage by rail of dangerous goods (RID) - attachment to appendix C of the convention concerning international carriage by rail (COTIF) dated May 09, 1980 (Federal Law Gazette 1985 II pg. 130) in the version published on May 16, 2008 (Federal Law Gazette 2008 II pg. 475), last modified by the 17th RID amendment dated November 9, 2012 (Federal Law Gazette 2012 II pg. 1338).

Attachment to the European Accord dated May 26, 2000 on the international carriage of dangerous goods by inland waterways (ADN) (Federal Law Gazette, 2007 II pg. 1906), last modified by the 4th ADN amendment dated December 3, 2012 (Federal Law Gazette 2012 II pg. 1386),

Ordinance on the domestic and international carriage of dangerous goods on road, by rail, and on inland waterways (GGVSEB) in the version published on January 22, 2013 (Federal Law Gazette 2013 I pg. 110),

International Maritime Dangerous Goods Code (IMDG-Code), Amendment 35-10,

Ordinance on the carriage of dangerous goods by sea (GGVSee) in the version published on December 16, 2011 (Federal Law Gazette 2011 I pg. 2784, 2012 I pg. 122), modified by article 4 of the ordinance dated December 19, 2012 (Federal Law Gazette 2012 I pg. 2715),

International Civil Aviation Organization - Technical Instructions for the Safe Transport of Dangerous Goods by Air, Edition 2013/2012,

Regulations on Certification and Licensing in Aviation in the version published on July 10, 2008 (Federal Law Gazette 2008 I pg. 1229), last modified by article 2 of the ordinance dated February 15, 2013 (Federal Law Gazette 2013 I pg. 293), in combination with the ICAO Technical Instructions,

In combination with the Federal Ministry of Transport, Building and Housing (BMVBS) guidelines in the version published on November 17, 2004 (VkBl. 2004 pg. 594) and the BMVBS bulletin on guidelines for the dangerous goods regulations dated July 1, 2010 (VkBl. 2010 pg. 282).

It is confirmed that the Federal Office for Radiation Protection, Salzgitter, is the agency authorized by the Federal Ministry of Transport, Building and Housing in accordance with section 7.9 of the IMDG code.

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Approval holder: NTP Radioisotopes (Europe) S. A.
Zoning Industriel
Avenue de l'Esperance
B-6220 Fleurus, Belgium

Documentation: GammaMat TI, TI-F and TI-FF, Renewals as B(U)-85, June 2013, with Table of Contents GammaMat TI, GammaMat TI-F, GammaMat TI-FF, (file number: JL130611)

Number of the package: **D/2012/B(U)-85**

Validity of the approval: **Up to and including June 30, 2016**

Allowable contents:

caesium-137	max. activity: 0.37 TBq or
iridium-192	max. activity: 3.7 TBq or
ytterbium-169	max. activity: 3.7 TBq or
thulium-170	max. activity: 3.7 TBq

respectively in a SPECIFIC FORM.

Package design:

As per the inspection certificate from the Federal Institute for Materials Research and Testing (BAM), dated September 10, 1981 (file number 1.2/11714, 1.2/11720) and according to the BAM expert review dated December 08, 1989 (file number: 1.52 Ma/Sei), the BAM letter dated 09.12.1992 (file number: 9.31/Nz), dated 29.09.1995 (file number: III.33/Nz), dated 02.12.1998 (file number: III.32/Nz, dated 22.11.2000 (file number: III.32/Nz), and dated 07.02.2001 (file number: III.32/Nz), and with regard to radiation shielding according to testing by the Federal Office for Radiation Protection (BfS), the GammaMat TI-F design meets the requirements imposed for type B(U) packages by the Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended 1990) by the International Atomic Energy Agency (IAEA). With the BAM report dated 04.03.2004 (file number: III.32/Dau), dated 19.12.2006 (file number: III.3/21210), dated 25.09.2009 (file number: III.3/21327), including the addendum dated 15.12.2009, dated 20.12.2012 (file number: 3.3/21477-1), and dated 14.06.2013 (file number: 3.3/21513-1) and according to BfS testing, it is confirmed that the requirements for continued use of the type B(U) package according to the interim regulation §817 of the Regulations for the Safe Transport of Radioactive Material, 2009 Edition, International Atomic Energy Agency (IAEA), No. TS-R-1, have been met.

Description of the packaging:

The shielding out of depleted uranium is permanently installed in a cylindrical stainless steel shell equipped with a handle and base. A fully enclosed guide tube which can be opened with a control button equipped with a safety lock serves to receive the source and source holder. The control button is covered with a protective cap. The GammaMat TI-F design is approved in the versions Va, version 101.10, version 101.11 and version 101.13.

Dimensions and drawings:

	Version Va	Version 101.10 and Version 101.11	Version 101.13
Height	167 mm	167 mm	167 mm
Width	110 mm	110 mm	110 mm
Length	251 mm	243 mm	257 mm
Mass (approx.)	15.5 kg	15.5 kg	16 kg

Drawings:

Version Va:
Drawing number: TI 100.00 Va dated 11.06.1969 up to the revision index "f"

Version 101.10 and 101.11:
Drawing number: 101.10-000 and 101.11-000 dated 28.08.1980

Version 101.13:
BOM number: TI 101.13-000, page 1 index "F" dated 10.11.2000, page 2 index "F" dated 15.08.2000 and page 3 index "C" dated 15.08.2000 with the associated assembly drawing: TI 101.13-000 index "B" dated 27.03.2000

Source holder:
Drawing number: K 126204-005 index "B" dated 02.05.2006 with BOM No.: K 126204-005 index "B" dated 02.05.2006

Collateral clauses and considerations:

1. All measures to ensure quality during the planning, accompanying inspections, and operation must be performed according to the stipulations of the BAM dangerous goods regulation "Quality Assurance Measures of Packagings for Competent Authority Approved packages for the Transport of Radioactive Material " (BAM-GGR 011, Rev. 0).

2. Re-manufacturing of packages is prohibited.

3. This approval applies to packages up to the serial number 1620 without inspection certificate and from serial number 1620 inclusive only in combination with an inspection certificate prepared for the respective production sample. Copies must be sent unsolicited to the BAM and the BfS. The deviations tolerated by BAM according to TRV 006 as well as modifications according to collateral clause no. 8 must be documented in this inspection certificate. For production samples which have already been produced, the deviations tolerated by BAM and the modifications according to collateral clause no. 8 must be documented in the production sample test book.

4. It is necessary to ensure that every user of the packaging have themselves registered with the BfS before using the packaging for the first time, and that he/she confirms that they have received and will observe the test book, which in particular contains the approval certificate, the user and maintenance manuals, and the inspection plan for recurrent inspections. The 6th revision of the user manual dated March 2013 (file number: SM4050.CON (v006)) and the plan for periodic and/or unplanned inspections, rev. 3 dated 23.05.2013 in combination with the checklist for maintenance and repairs (D003-de), version 003 dated May 2013, are mentioned specifically. The use of documents with a higher revision index is only permissible within the framework of this approval following BAM approval and approval by the BfS in the form of an endorsement.

5. Each time before transporting the package, it is necessary to ensure that the guide tube is closed and the protective cap is installed and secured.

6. Every production sample must be permanently marked with the aforementioned label and with the date (month and year) of the next periodic inspection.

7. Every production sample must be subjected to periodic inspections on time. For production samples which are used outside of the Federal Republic of Germany, the periodic inspections can also be performed and certified by inspection personnel authorised by the responsible agency of the respective country. The certificates for the performed periodic inspections must be sent unsolicited to the BAM and the BfS.

8. Changes with regard to the drawings, BOMs, and material data sheets on which the approval is based must be approved by the BfS in the form of an endorsement after approval by the BAM and before the start of fabrication. Modifications performed on this basis to production samples for which a final inspection certificate has already been issued and to production samples up to the serial number 1620 (see collateral clause 3) must be documented in the respective test book.

9. Special measures during transport are not required.

10. This approval doesn't release the consignor from the obligation of adhering to any regulations of a government of any state into or through which the package is being transported.

11. Use of the package for international transport is subject to the requirements of the multilateral approval process according to § 817 of the Regulations for the Safe Transport of Radioactive Material, 2009 Edition, International Atomic Energy Agency (IAEA); No. TS-R-1. Therefore approval of the package by the responsible agencies of all countries affected by the transport is required.

12. The transfer of ownership of the approval to a third party requires the prior written consent of the BfS. For this purpose, the following documents must be submitted to the BfS at least 4 weeks before the intended transfer: An agreement between the current and future holder of the approval which attests to the transfer of all rights and obligations associated with the approval, the quality management system of the future approval holder and the associated quality assurance program for the affected design, which need to be approved by the BAM according to the BAM-GGR 011 Rev. 0 requirements.

Costs:

1. Costs, fees, and expenses are charged for this report on the basis of §12 paragraph 1 and 2 of the law on the transport of dangerous goods (Gefahrgutbeförderungsgesetz - GGBefG) in the version published on July 7, 2009 (Federal Law Gazette 2009 I pg. 1774, amended pg. 3975), in combination with §1 paragraph 2 of the regulation concerning the costs involved with transporting dangerous goods (Gefahrgutkostenverordnung - GGKostV) dated March 7, 2013 (Federal Law Gazette 2013 I pg. 466). The fees are determined according to § 2 in combination with appendix 2 of the GGKostV.

2. In accordance with §12 paragraph 1 of the GGBefG in combination with §13 paragraph 1 no. 1 of the Administrative Costs Act (VwKostG) dated June 23, 1970 (Federal Law Gazette 1970 I pg. 821), last modified by article 6 of the law dated December 05, 2012 (Federal Law Gazette I pg. 2415), the costs shall be borne by the company NTP Radioisotopes (Europe) S. A., Belgium.

3. The costs are assessed through a separate report.

Right of appeal:
An appeal to this report can be entered within one month of notification. The appeal must be entered with the Bundesamt für Strahlenschutz, Willy-Brandt-Straße 5, 38226 Salzgitter, in writing or to be written down.

Salzgitter, June 25, 2013

Im Auftrag

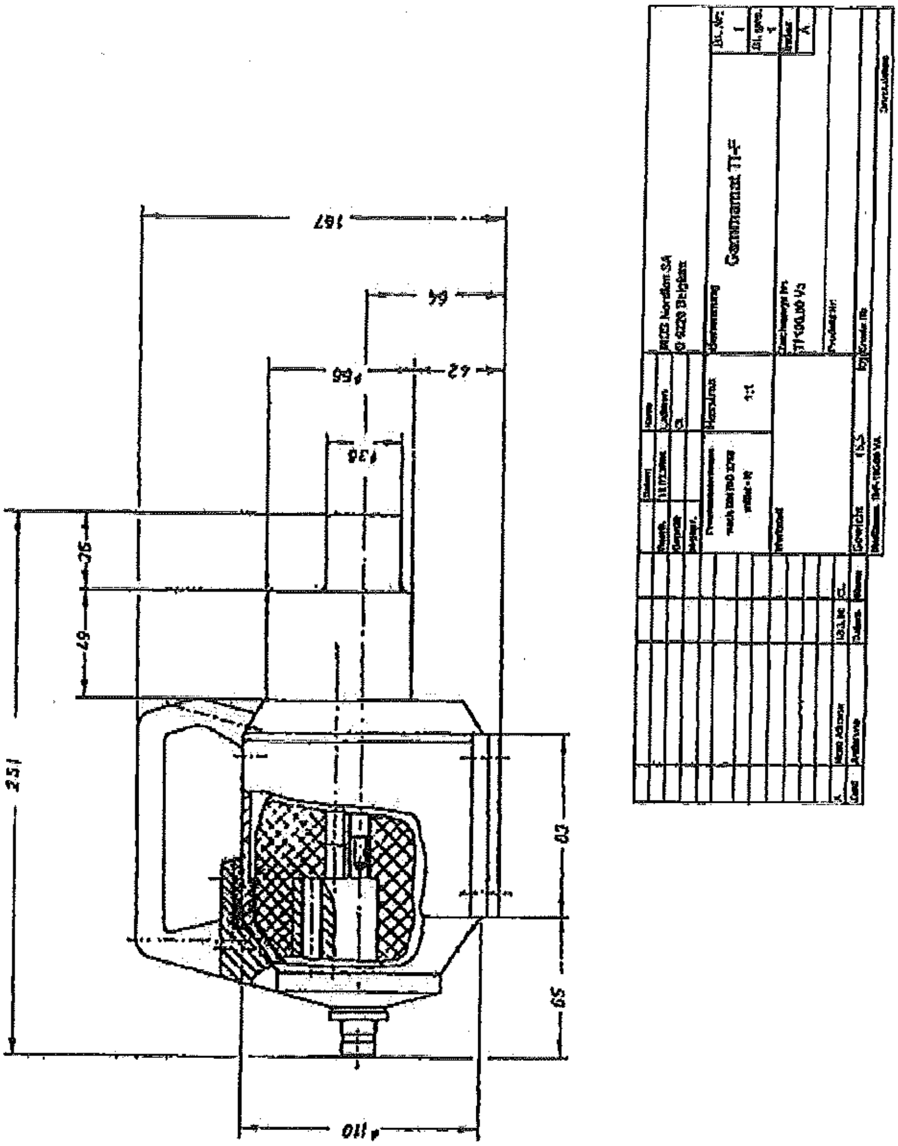
(Siegel)

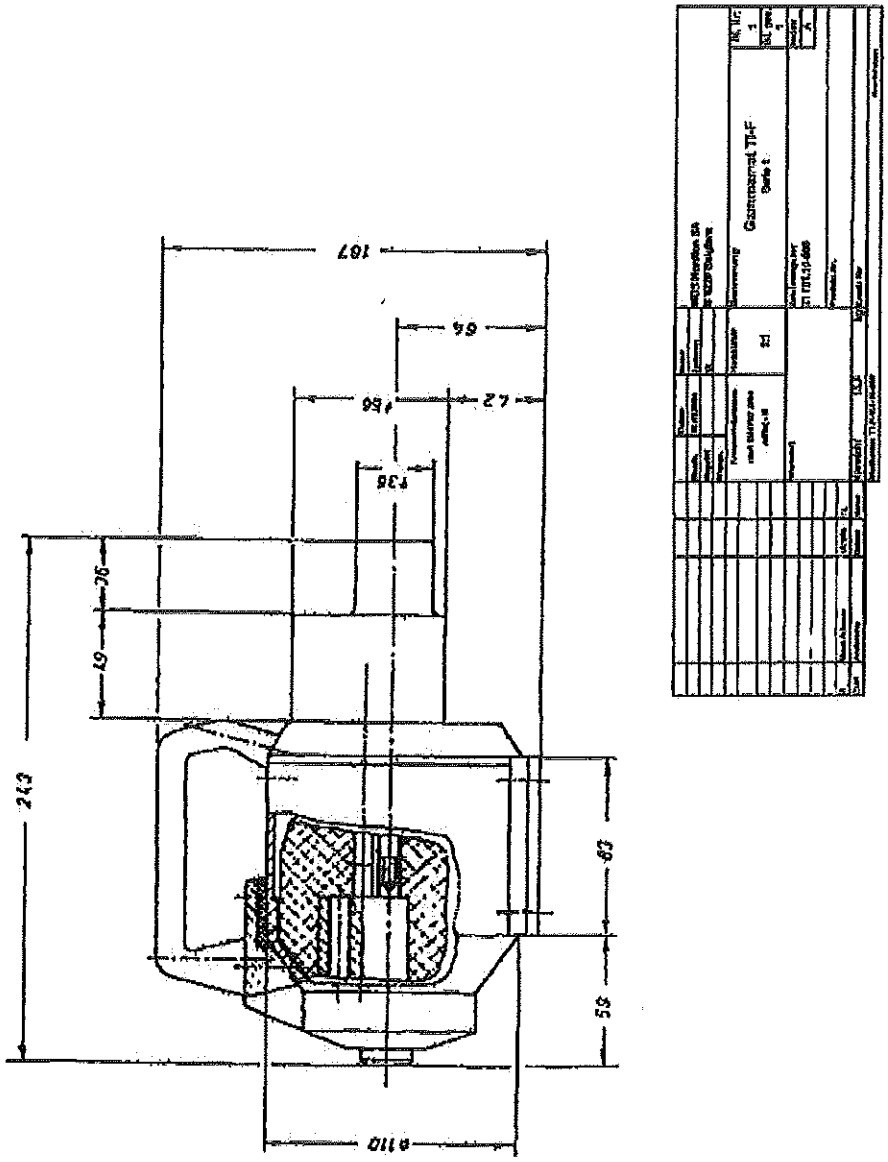
Müller, U.

Attachments
Appendix
Attachment with 3 overview illustrations by the company MDS Nordion S. A.
page 1 for the version Va
page 2 for the version 101.10 and 101.11, (Gammamat TI-F series 2) and
page 3 for the version 101.13 with the new drawing number K425602-001, Is. A.

- Attachment to the approval certificate D/2012/B(U)-85 (Rev. 14) –

Rev. No.	Date of issue	Valid up to and including	Reason for the revision
0	01.02.1979	01.02.1982	Initial version
1	03.07.1980	03.07.1983	Extending the validity, modification of the content
2	07.03.1983	07.03.1986	Extending the validity, addition of the design versions TI-F 101.10 and TI-F 101.11
3	06.03.1986	28.02.1989	Extending the validity, addition of the design version TI-F 101.13-000
4	20.02.1989	28.02.1992	Extending the validity, modification of the requirements
5	21.12.1989	31.12.1992	Extending the validity, additional quality assurance measures
6	14.12.1992	31.12.1995	Extending the validity, changes to the traffic regulations, amending the collateral clauses and the identifier
7	21.12.1995	31.12.1998	Extending the validity, amending the collateral clauses
8	14.12.1998	31.12.2001	Extending the validity, changes to the traffic regulations
9	20.03.2001	20.03.2004	Extending the validity, new approval holder, revision of the BOMs and drawings, revision of the collateral clauses,
10	18.03.2004	31.12.2006	Extending the validity, adaptation to modified legal requirements, new approval holder, new user manual, new quality management system, revision of the collateral clauses
11	05.01.2007	31.12.2009	Extending the validity, quality management system revised, amending the collateral clause 2, adaptation to modified legal requirements, new source holder BOM
12	18.12.2009	31.12.2012	Extending the validity, quality management system revised, adaptation to modified legal requirements
13	21.12.2012	30.06.2013	Extending the validity, new approval holder, documentation revised, adaptation to modified legal requirements, new collateral clause no. 12
14	25.06.2013	30.06.2016	Extending the validity, new approval holder, documentation revised, adaptation to modified legal requirements.

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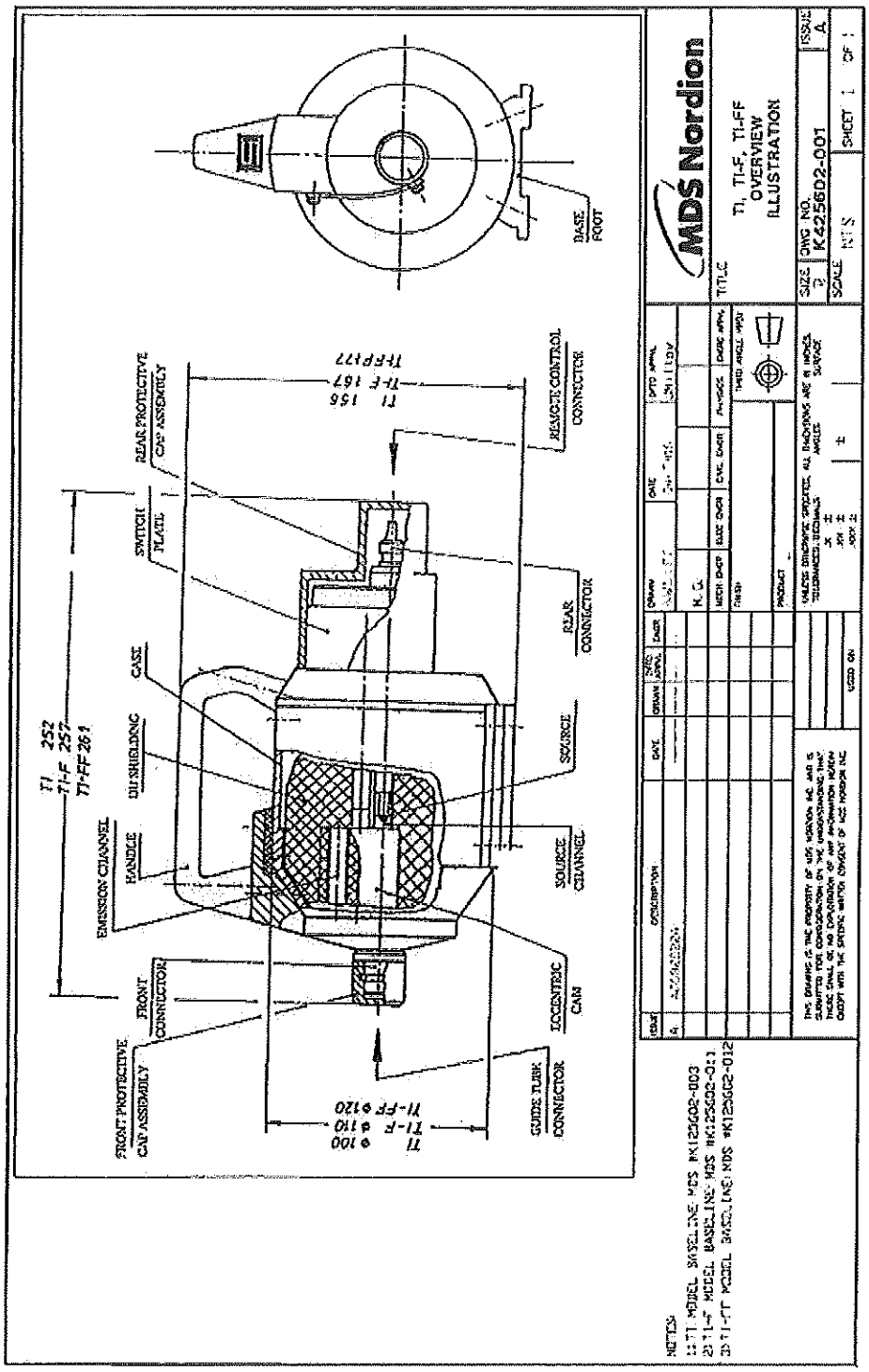
MDS Nordion
TI, TI-F, TI-FF
OVERVIEW
ILLUSTRATION
K4256D2-001
BASE
FOOT
REAR PROTECTIVE
CAP ASSEMBLY
SWITCH
PLATE
CASE
SHIELDING
HANDLE
EMISSION CHANNEL
FRONT
CONNECTOR
FRONT PROTECTIVE
CAP ASSEMBLY
REMOTE CONTROL
CONNECTOR
REAR
CONNECTOR
SOURCE
SOURCE
CHANNEL
ECCENTRIC
CAM
GUIDE TUBE
CONNECTOR
TI 252
TI-F 252
TI-FF 261
TI 156
TI-F 167
TI-FF 177
TI ⌀100
TI-F ⌀110
TI-FF ⌀120