
**Measurement and prediction of the
ambient dose equivalent from patients
receiving iodine 131 administration
after thyroid ablation —**

**Part 2:
External effective dose of the
caregivers after release from the
hospital**

*Mesurage et prévision de l'équivalent de dose ambiant de patients
bénéficiant d'un traitement par iode 131 après ablation de la
thyroïde —*

*Partie 2: Dose externe efficace des proches après sortie
d'hospitalisation*



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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

A list of all the parts in the ISO 18310 series can be found on the ISO website

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 18310 series addresses methods and procedures for measuring ambient dose equivalent from patients administered ^{131}I for thyroid cancer therapy.

Thyroid cancer can be treated by administering radioiodine with the remnants after surgery, because radioiodine selectively accumulates in thyroid tissue to irradiate and kill the cancerous cells. Thyroid cancers are small and are not likely to develop into aggressive malignancies. Earlier diagnosis and treatment can remove these cancers at a time when they are not likely to have spread beyond the thyroid gland.

There are two common practices for the treatment of thyroid cancer: One is a radioiodine administration without thyroid resection. The other is administration after thyroid resection. In recent years, the radioiodine administration after surgery has become more common as radioiodine selectively accumulates in thyroid tissue to irradiate and kill the cancerous cells.

The most commonly used radionuclide for the treatment is ^{131}I . ^{131}I is a radioisotope that emits gamma rays following beta decay. The primary emissions of ^{131}I decay are thus electrons with a maximal energy of 606 keV (89 % abundance, others 248 keV – 807 keV) and 364 keV gamma rays (81 % abundance, others 723 keV). Since the abundance of 364 keV gamma-ray is much greater than other gamma-ray energies, the main contribution to the ambient dose equivalent is from 364 keV gamma-ray. Its radiological half-life is 8,02 d. The iodine is administered orally and is absorbed in the gastrointestinal tract. Most iodine subsequently travels through the blood and is available in the circulation for uptake by the thyroid gland and urinary excretion; the remainder is excreted in faeces, sweat, saliva and breast milk in organic form.^[1] For patients who have had their thyroid removed, the retention time in the body is shorter than that of patients who have not had their thyroid removed.

Patients who receive radioiodine treatment for thyroid cancer emit radiation and represent a potential hazard to other individuals. Critical groups among the public are fellow travellers on the patient's trip back home from the hospital, members of the patient's family, close friends, caregivers and comforters.

For the purpose of the ISO 18310 series, this document focus on the determination of the effective dose to the caregiver in the vicinity of the patient treated with radioiodine. It is based on the estimation of the effective dose using a personal dosimeter worn by the caregiver. The uncertainty of the effective dose is also provided.

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Measurement and prediction of the ambient dose equivalent from patients receiving iodine 131 administration after thyroid ablation —

Part 2:

External effective dose of the caregivers after release from the hospital

1 Scope

This document addresses the measurement methods, procedures and uncertainty estimation for the measurement, using a personal dosimeter, of the effective dose to the caregiver in the vicinity of the patient treated with radioiodine to ablate the thyroid.

The general requirements for the patient and caregiver and a guidance (see [Annex A](#)) for designated expert on instructing caregivers of discharged patients is considered to effectively measure the effective dose to the caregiver in the vicinity of the patient.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4037-1, *Radiological protection — X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 1: Radiation characteristics and production methods*

ISO 4037-2, *Radiological protection — X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 2: Dosimetry for radiation protection over the energy ranges from 8 keV to 1,3 MeV and 4 MeV to 9 MeV*

ISO 4037-3, *Radiological protection — X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 3: Calibration of area and personal dosimeters and the measurement of their response as a function of energy and angle of incidence*

ISO 4037-4, *Radiological protection — X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 4: Calibration of area and personal dosimeters in low energy X reference radiation fields*

ISO 18310-1, *Measurement and prediction of the ambient dose equivalent from patients receiving iodine 131 administration after thyroid ablation — Part 1: During the hospitalization*

ISO 29661, *Reference radiation fields for radiation protection — Definitions and fundamental concepts*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4037-1 to ISO 4037-4, ISO/IEC Guide 99, ISO 29661 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

caregiver

individual such as a family member, close friend, or accompanying person who willingly and voluntarily takes care of a discharged patient treated with radioiodine to ablate the thyroid remnants

3.2

calibration

operation under specified conditions that, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

3.3

effective dose

tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body

3.4

electronic personal dosimeter

EPD

electronic device used for continual monitoring with live readout of accumulated radiation dose due to ionizing radiation

3.5

optically stimulated luminescence dosimeter

OSLD

radiation dosimeter used to measure ionizing radiation exposure from electrons trapped between the valence and conduction bands in the crystalline structure of certain minerals by optical stimulation of the material to emit light of a different wavelength

3.6

personal dosimeter

device, such as an *electronic personal dosimeter* (3.4), *optically stimulated luminescence* (3.5), *radiophotoluminescent glass dosimeter* (3.8) or *thermoluminescent dosimeter* (3.9), used for monitoring the personnel cumulative radiation dose due to ionizing radiation

3.7

^{131}I

iodine 131 (^{131}I) that decays with a half-life of 8,02 d with beta and gamma emissions

Note 1 to entry: On decaying, ^{131}I most often (89 % of the time) expend 971 keV of decay energy by transforming into stable ^{131}Xe in two steps with gamma decay following rapidly after beta decay. The primary emissions of ^{131}I decay are beta particles with maximum energy of 606 keV and gamma rays of energy 364 keV. Major application of ^{131}I is for the direct radioisotope therapy to treat hyperthyroidism and some types of thyroid cancer.

3.8

radiophotoluminescent glass dosimeter

RPLD

radiation dosimeter which uses glass compound as the luminescent material

3.9 thermoluminescent dosimeter TLD

radiation dosimeter used to measure ionizing radiation exposure from electrons trapped between the valence and conduction bands in the crystalline structure of certain minerals by measuring the intensity of light emitted from a crystal in the detector when the crystal is heated

4 General requirements for the release of patient with caregiver

4.1 Discharge criteria

Discharge of an in-patient treated with ^{131}I is permitted only if the dose to family, close friends, and third persons due to the residual activity in the patient is not expected to exceed dose constraints approved by the competent authorities.

The recommendations by the International Commission on Radiological Protection (ICRP) and the standards of International Atomic Energy Agency (IAEA) stipulate a dose limit of 1 mSv/y to the general public and 5 mSv per treatment to relatives, visitors, and caregivers of patients upon release of patients treated with radionuclide from hospitals. Further, ICRP 94^[2] recommends applying an annual dose limit of 1 mSv to embryos/fetuses, infants, and children, which is a small group with higher sensitivity, in lieu of a dose limit of 5 mSv per treatment.

The Nuclear Regulatory Commission (USNRC) in the United States indicates in Table 1 of Reference [3] that the derived residual radioactivity of 1,2 GBq or a spatial dose rate of 70 $\mu\text{Sv/h}$ at a distance of one metre computes to an effective dose of 5 mSv to other persons at isolation or release of patients from the hospital.

Certain requirements should be met when discharging the patient. The responsible designated expert is to ensure that relevant dose measurements are performed, and that instructions are given to patients, both orally and in writing. The designated expert is to ensure that the patient comprehends the instructions to reduce exposure to other persons, as well as living conditions at home.

4.2 Management procedures of the patient receiving ^{131}I administration

The management procedures for the patient before, during and after treatment with radioiodine are as follows:

- Isolate the patient and restrict the patient and visitors from entering and exiting the room during the radioactive iodine treatment. During the hospitalization, the patient is not allowed to leave their room, and visitors are not allowed.
- Increase fluid intake during hospitalization and after discharge. Instruct the patient to urinate often even though there is no urge to urinate and to flush the toilet twice after urination or faecal discharge.
- While the responsible designated expert continues to process the patient's discharge, the patient may stay in the ward and go home directly after discharge.
- Instruct the patient either to use personal, separate cutlery and crockery or eat off disposable plates, cups and kitchenware, to use separate towels and bathing goods, and to wash hands clean all the time. Also, they should avoid places with many people such as movie theatres, stores or public transportation.

4.3 Release from the medical facility

As a general rule, the treatment of thyroid cancer using radioiodine is performed only in conjunction with the hospitalization of the patient in some countries. In this case, the discharge of a patient shall be in accordance with the requirements of the regulatory body.

Before discharging a patient from a medical facility, the designated expert shall ensure that the residual activity does not exceed regulatory limits. This shall be done by dose measurements performed at 1 m from the standing patient in accordance with ISO 18310-1.

The instructions of [A.2](#) and [A.3](#) may be given to a released patient and their caregiver.

[A.4](#) is a sample letter of consent by the patient or their legal guardians, including the caregiver.

4.4 Responsibility of the designated expert

The designated expert responsible for the treatment and discharge should ensure that the instructions are understood and followed by the patient and caregiver. The patient should be self-sufficient and capable of co-operating and complying with the instructions. The caregiver is to ensure the patient follows the instruction.

One of the factors to be evaluated for the discharge of patients is the home environment in a socio-economic sense, which should be such as to allow the patients and caregivers to comply with the instructions received. Consideration should be given to the available living space, i.e., the number of rooms in the house, quality of sanitary installations, connection to main sewerage, etc.

5 Measurement of the effective dose to the caregiver

5.1 General

Radioiodine is a common and effective treatment for thyroid cancer. There are, however, significant radiation protection issues associated with treatment. These include emitted radiation and the loss of radioiodine through urine, faeces, sweat, saliva and breast milk. Those at potential risk of being irradiated include members of the public and caregivers with whom the patient may come into close proximity.

5.2 Specifications of the personal dosimeter

The effective dose to the caregiver in the vicinity of the patient treated with radioiodine is measured by a personal dosimeter, such as EPD, OSLD, RPLD or TLD.

The personal dosimeter should have a uniform energy response for the energies of ^{131}I and have a minimum detectable value of 0.01 mSv. The dosimeter should be analysed by an approved dosimetry service in accordance with local regulations.

5.3 Measurement of the effective dose to the caregiver

Procedures for the caregiver using a personal dosimeter after release from the hospital shall be performed as follows:

- a) Attach a personal dosimeter, which has a uniform energy response for the energies of ^{131}I , to the chest of the caregiver (e.g. husband, wife or comforter).
- b) The caregiver should always wear the personal dosimeter when with the patient.
- c) The patient should follow instruction given by the hospital after returning home (see [A.3](#)).
- d) The caregiver should not be in contact with or near the patient except when providing normal care, for example, serving of meals or administering medication.
- e) The caregiver should sleep in a separate bed room.

The caregiver should return to the hospital on a designated date to turn in the dosimeters.

The detailed procedure for measuring the effective dose to the family of the patient receiving ^{131}I administration is given in [A.1](#).

The measurement results for the effective dose to the caregiver are shown in [Annex B](#).

6 Quality control

The personal dosimeter shall be calibrated periodically by a laboratory conforming the requirements of ISO/IEC 17025. As per the Bureau International des Poids et Mesures (BIPM) report, the stability of the calibration coefficient of the personal dosimeter shall be maintained within 5,0 %.

7 Uncertainty

The uncertainty, U , for the determination of the measurement of the effective dose from patients administered with ^{131}I consists of the following [Formula \(1\)](#):

$$u_c(H_c) = \sqrt{u^2(N_r) + u^2(M) + u^2(r) + u^2(K) + u^2(\Gamma) + u^2(Q_0) + u^2(\lambda) + u^2(T_r) + u^2(T_m)} \quad (1)$$

where

- $u(N_r)$ uncertainty of calibration factor of the detector from the calibration certificate;
- $u(M)$ uncertainty of measurement of the effective dose for ^{131}I ;
- $u(r)$ uncertainty of the ratio of the conversion coefficients between ^{131}I obtained from the interpolation of photon energy versus conversion coefficient fit function and the reference radiation;
- $u(K)$ uncertainty of positioning of the chamber for ^{131}I ;
- $u(Q_0)$ uncertainty of initial administration dosage of ^{131}I ;
- $u(T_r)$ uncertainty of admission period;
- $u(T_m)$ uncertainty of nursing period;
- $u(\lambda)$ uncertainty of effective removal constant of ^{131}I ;
- $u(\Gamma)$ uncertainty of patient rate coefficient.

Annex A **(informative)**

Examples of written instructions to be presented to patients or their legal guardians before leaving the hospital after treatment with radioiodine

A.1 Procedure for measuring radiation exposure to the caregiver of the patient receiving radiation treatment

- a) As the patient who received ^{131}I greater than 1,1 GBq (30 mCi) for the radioactive iodine treatment is discharged, the radiation exposure to the caregiver is to be measured with a personal dosimeter.
- b) Personal dosimeter is provided to the one person who is primarily responsible for the care of the patient around 9 a.m. of the day of discharge.
- c) Instruct the caregiver to wear the personal dosimeter directly on their chest with the front of the dosimeter facing outward and to keep it in this position at all times until it is returned. Instruct the caregiver to place the personal dosimeter on the bedside during sleep and to attach the dosimeter again in the morning before seeing the patient.
- d) Instruct the caregiver to place the personal dosimeter beyond the patient's reach when leaving the home without the patient.
- e) Medical staff who provide the personal dosimeter should write down the radioactivity of the treated radioactive iodine, date of treatment, personal dosimeter number, date of discharge and date of personal dosimeter return. The caregiver is instructed to hand in the personal dosimeter with a completed questionnaire when visiting the hospital at the end of the period of use (7 to 9 days depending on the patient's measured exposure rate at time of discharge).
- f) Collected personal dosimeters are sent to an external approved dosimetry service for personal dosimeter readings.

A.2 Recommended instructions for caregiver

- a) This dosimeter is a device to measure the radiation exposure to your body.
- b) The dosimeter is worn on your chest with the front face of the dosimeter being placed outward. It should be worn in this position at all times. Do not wear it on the back of your body or in a rear pocket.
- c) The dosimeter is worn on the outermost article of clothing and care should be taken that the front face of the dosimeter is not covered.
- d) Place the dosimeter at your bedside during sleep.
- e) If you are going out without the patient, place the dosimeter in a cool, dry place away from the patient.
- f) Be careful not to wet, destroy, or lose the dosimeter.
- g) Return the dosimeter to the hospital at follow-up treatment visit.

A.3 Precautions after discharge for patients and caregivers

- a) When the patient is going home by a privately owned car driven by the caregiver, the patient and caregiver shall sit diagonally away from each other (i.e., patient sits behind the front passenger seat). If the patient has to use public transportation, the patient should sit as far from other passengers as possible.
- b) The patient should try to avoid crowded places.
- c) The patient should avoid physical contact with other members of the family, maintaining a distance of 1 m from them and keeping the contact time with them to less than 1 h.
- d) The patient should avoid direct contact with pregnant women and children.
- e) The patient should use an isolated bedroom or sleeping area for 2 weeks after discharge. If the patient shares a bedroom with another person, they should use separate beds and sleep at least 2 m away from others.
- f) The patient should use separate towels, bathing goods, cups, plates and kitchenware from those of the rest of the family for at least two 2 weeks.
- g) The patient should eat off a personal plate at meal times and regularly wash their hands.
- h) The house should be ventilated frequently.

A.4 Letter of consent

- a) I have read the guidelines regarding the prospective clinical trial for the measurement of the radiation exposure to the caregiver of the patient who received radioactive iodine treatment after the patient's discharge using a personal dosimeter, and I fully understand the content of the guidelines.
- b) I was provided with information on the purpose, plan, process and possible risk of this clinical trial. I am fully aware that the clinical staff is responsible for providing information regarding not only the possible risk but also any additional information about the clinical trial during and after my participation in this clinical trial.
- c) I am voluntarily participating in this clinical trial.
- d) I give my consent that the materials obtained by this clinical trial can be anonymously transferred to the clinical staff designated by the health and permission authority. I agree that the clinical staff can have direct access to the original medical records for verification of the imaging test procedure and (or) materials without violating confidentiality.
- e) I am aware that I cannot participate in this clinical trial if I receive any medical treatment involving radioactive material other than under this clinical trial, if I cannot comply with this clinical trial proposal, or if I am excluded from the selection criteria for clinical trial subjects.
- f) I can decline participation or stop participating in the clinical trial at any time. I am also aware that the discontinuation of my involvement in this clinical trial cannot result in any disadvantage to me
- g) In the requirements of this clinical trial, I agree that materials collected in the clinical trial, including racial lineage, can be processed by a computing system on behalf of the commission or the clinical staff. By law, I have a right to access the materials and to modify them together with the clinical staff at any time
- h) I honestly answered all the questions regarding my medical history, and I declare that I adhere to all the rules and regulations that are imposed on me by my doctor and that are described in the instructions for the clinical trial subject.

- i) I choose to participate in the clinical trial of my own free will, and I will receive copies of the instructions for the test subject and the letter of consent.

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Annex B (informative)

Experimental application to this document: measurement and prediction of the effective dose to the caregiver in the vicinity of the patients receiving radioiodine ^{131}I administration after thyroid ablation

B.1 General

This document aims at measuring the effective dose from gamma radiation received by the caregiver in the vicinity of a patient who received ^{131}I after thyroid resection.

The effective dose to the caregiver in the vicinity of the patient receiving high-dose of ^{131}I treatment to ablate the thyroid is measured using a personal dosimeter in accordance with the document. Based on real experimental data, the prediction equations of the caregiver in the vicinity of the patient are proposed based on the administered activity.

B.2 Estimation of the effective dose to the caregiver

The dose rate over time is reduced exponentially at a certain distance from the ^{131}I administered thyroid cancer patient after thyroidectomy.

The following [Formula \(B.1\)](#) shall be used when measuring the external exposure dose from the reference distance of 1 m for a period from the point of leaving the hospital, T_r , until the monitoring termination point, T_m , after administering certain dosage of ^{131}I to patients after the thyroidectomy. It is allowed to define the external exposure dose as an integrated dose rate of $\dot{H}_o(t)$ for the period at the distance of reference.

$$H_o = \int_{T_r}^{T_m} \dot{H}_o dt \quad (\text{B.1})$$

If there is a certain pattern of exposure conditions between the caregiver and patient, it is allowed to link dose at the reference distance, H_o , and the actual dose of the caregiver, H_c , with a certain parameter K . This means that when [Formula \(B.2\)](#) below is realized, and K exists and is an assumed factor for quantification, the value shall be as given by [Formula \(B.3\)](#):

$$H_c = K \cdot H_o \quad (\text{B.2})$$

$$K = \frac{H_c}{H_o} \quad (\text{B.3})$$

Meanwhile, the dose rate at a unit distance of 1 m from the ^{131}I -administered patient can be obtained as given in Formula (B.4) following ISO 18310-1:2017, Formula (A.1):

$$\dot{H}_o(t) = \Gamma Q_0 e^{-\lambda t} \quad (\text{B.4})$$

where

Γ is a constant representing the ambient dose equivalent rate at a distance of 1 m from the patient per administration of unit radioactivity (GBq) and calculated as $4,287 \times 10^{-2} \text{ mSv h}^{-1} \text{ GBq}^{-1}$ with ISO 18310-1:2017, Formula (A.1). The constant Γ is called the 'patient dose rate coefficient' for convenience in this document;

Q_0 is the initial administration dosage of ^{131}I (GBq);

λ is the effective removal constant of ^{131}I .

When applying the effective half-life of 13,86 h (= 0,578 d) of ^{131}I of the thyroidectomy patient, $0,05 \text{ h}^{-1}$ (= $1,2 \text{ d}^{-1}$) can be used as an effective removal constant.

When the dose rate formula containing the patient dose rate coefficient, Γ , is linked with [Formula \(B.1\)](#), it is allowed to derive a formula for predicting the dose to third party persons in the vicinity of the patient dependent upon the radioactivity administered to the patient. The external dose, H_c , exposed to the caregivers of the patients after release from the hospital can be estimated as follows from the initial administration dosage of ^{131}I , Q_0 , admission period, T_r , and dose assessment (nursing) period, T_m given by Formula (5):

$$H_c = K \cdot H_o = K \int_{T_r}^{T_m} \dot{H}_o dt = K \cdot Q_0 \cdot \Gamma \int_{T_r}^{T_m} e^{-\lambda t} dt = \frac{K \cdot Q_0 \cdot \Gamma}{\lambda} [e^{-\lambda T_r} - e^{-\lambda T_m}] \quad (\text{B.5})$$

B.3 Summary of measurement

Depending on the symptoms severity, data for more than 30 caregivers of patients treated with high activity ^{131}I ranging from 1,85 GBq to 5,55 GBq (50 mCi to 150 mCi) after thyroid resection are used for this clinical trial.

After release from the hospital, the patient and his (her) caregiver should stay in the same house, and caregiver should always wear a personal dosimeter positioned on the chest until the personal dosimeter is returned when the caregiver returns to the hospital for follow-up.

The details of the Institutional Review of Board (IRB) protocol were explained to the patient and their caregivers and they signed a written consent regarding their participation in the clinical trial.

B.4 Result

For patients treated with ^{131}I to ablate the thyroid, the measurements of the effective dose to their caregivers are given in [Table B.1](#).

Table B.1 — Measurement result of the effective dose to the caregiver

No	Patient		Hospitalization activity GBq (mCi)	Hospitalization period h	Dose rate at release $\mu\text{Sv/h}$	Care period h	Caregiver			
	Sex	Age					Sex	Age	Relation-ship	Effective dose mSv
1	F	66	3,7 (100)	40	9,9	150	M	67	Spouse	0,01
2	M	56	2,96 (80)	40	6,1	151	F	52	Spouse	0,05
3	F	31	3,7 (100)	40	0,2	195	F	56	Mother	0,01
4	F	35	3,7 (100)	41	29,2	172	F	64	Mother	0,01
5	F	52	3,7 (100)	41	3,6	173	M	60	Spouse	0,01
6	F	49	3,7 (100)	42	12,0	168	M	65	Spouse	0,04
7	F	62	3,7 (100)	41	11,8	172	M	66	Spouse	0,01