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**Risks associated with the lay use of
'over-the-counter' medical devices**
- Study on infrared thermometers and wound care products -

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Abbreviations

FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis
IGZ	Dutch Health Care Inspectorate
IR	Infra-red
IVDD	In Vitro Diagnostic Medical Devices Directive
MDD	Medical Devices Directive
OTC	Over-the-counter
PMS	Post-Market Surveillance
RIVM	Dutch National Institute for Public Health and the Environment
SMPE/e	School of Medical Physics and Engineering Eindhoven

Summary

An assessment of the files on two types of ‘over-the-counter’ medical devices (infrared thermometers and wound care products) revealed major shortcomings in the risk analyses, available user information and post-market surveillance procedures. These three components are important for guarding the safe use of a medical device, especially in terms of reducing risks as far as possible in the design stage of the device, informing the user of residual risks and undertaking post-market surveillance activities. Particularly for over-the-counter medical devices, a rapidly growing market segment, information for the (lay) user is important.

Application by lay users and potential errors when using the products were often not addressed in the risk analyses and were insufficiently covered in the user information. Moreover, the coherence between items addressed in the risk analyses and those stated in the user information was poor. The user information addressed more residual risks associated with the use of the product than the risk analyses. The comprehensibility of the user information was often compromised by poor readability and difficult phrasing. Appropriate user information is crucial for the safe application of self-care medical devices, even more so if the devices to be used are complex and/or relatively new to the consumer market. Files on 16 products – eight infrared thermometers and eight wound care products – were requested. These files contained the risk analysis, user information, post-market surveillance procedure and, if available, results of studies carried out with lay users. Files on all 16 products were received, but the documentation was often incomplete, notably for the thermometers. The absence of risk analyses and post-market surveillance procedures was remarkable as this information is an important requirement of the Medical Device Directive.

Samenvatting

Uit de beoordeling van dossiers van twee soorten ‘over-the-counter’ medische hulpmiddelen (infraroodthermometers en wondverzorgingsproducten) kwamen substantiële tekortkomingen naar voren in de risicoanalyses, de gebruikersinformatie en de post-market surveillance procedures. Deze drie onderdelen spelen een belangrijke rol in het waarborgen van het veilig gebruik van een product. Deze waarborging vindt plaats door risico’s zoveel mogelijk te beperken in de ontwerpfase van het product, door het informeren van de gebruiker over resterende risico’s en door post-market surveillance procedures te volgen. Met name voor ‘over-the-counter’ medische hulpmiddelen, een snel groeiend marktsegment, is informatie voor de (ongeoefende) gebruiker belangrijk.

Aan toepassing door ongeoefende gebruikers en aan mogelijke gebruiksfouten werd vaak geen aandacht besteed in de risicoanalyses en onvoldoende in de gebruikersinformatie. Bovendien was de samenhang tussen de onderwerpen in de risicoanalyses en de gebruikersinformatie matig. In de gebruikersinformatie werden meer resterende risico’s voor het gebruik van het product beschreven dan in de risicoanalyses. De begrijpelijkheid van de gebruikersinformatie werd vaak verminderd door slechte leesbaarheid en moeilijk taalgebruik. Goede gebruikersinformatie is heel belangrijk voor de veilige toepassing van medische hulpmiddelen voor zelfgebruik, vooral als de te gebruiken hulpmiddelen ingewikkeld en/of relatief nieuw voor de consumentenmarkt zijn.

Van 16 producten– 8 infrarood thermometers en 8 wondverzorgingsproducten- werd de documentatie opgevraagd. Deze documentatie omvatte de risicoanalyse, de gebruikersinformatie, de post-market surveillance procedure en, indien beschikbaar, de resultaten van studies uitgevoerd met leken. Voor alle producten werden dossiers ontvangen, maar deze documentatie was vaak incompleet, vooral van de thermometers. Het ontbreken van risicoanalyses en post-market surveillance procedures was opmerkelijk, aangezien de documenten belangrijke vereisten zijn in het Besluit medische hulpmiddelen.

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1 Introduction

1.1 Background

An increasing range of medical devices is used outside the controlled hospital environment, part of which is used at home. When these devices are accompanied by instructions intended for professionals, lay users may not be able to understand the medical device well enough due to their limited knowledge and experience. This may lead to use errors. Therefore, it is essential that instructions for home use devices are specifically developed for lay users (FDA, 2001), especially in the case of over-the-counter (OTC) medical devices, purchased by lay users for self-care without advice or prescription of a medical professional. Some examples of OTC medical devices are infrared thermometers, hydrocolloid wound dressings, blood pressure monitors, in vitro diagnostic self tests, rollators, contact lenses and contact lens care products.

The Directive for in vitro diagnostic medical devices (IVDD) contains specific requirements for in vitro diagnostic medical devices intended for self testing by lay users (cholesterol self test, pregnancy test kit for lay use etc.). The IVDD requires that “*Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment*” (Annex I, 7). Apart from this general requirement, the IVDD also requires that there should be a control method, allowing the user to verify if the product performs as intended (Annex I, 7.2) and that there should be a statement in the instructions for use that the user “*should not take any decision of medical relevance without first consulting his or her medical practitioner*” (Annex I, 8.7.t). Finally, the IVDD contains a requirement that there should be test reports of studies carried out with lay persons (Annex III, 6.1).

In contrast, the Medical Devices Directive (MDD) contains no specific legal requirements for medical devices intended for lay use, such as infrared (IR) thermometers, wound dressings or blood pressure monitors. However, the first general essential requirements of the MDD requires that “*The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety*”. Moreover, the standard NEN-EN-ISO 14971 states that “*Factors that should be considered include the intended user, the mental and physical abilities, skill and training of the user*”. Both these references imply that specific aspects related to medical devices for lay use should be taken into consideration by the manufacturer.

To evaluate the extent to which manufacturers have considered the use of their OTC product by lay users, the Dutch Health Care Inspectorate (IGZ) has requested the RIVM to investigate documentation held by manufacturers of two selected groups of OTC medical devices.

1.2 Scope

This survey investigates the extent to which manufacturers have considered the use of OTC medical devices by lay users as reflected in their documentation.

The practical use of OTC medical devices was not a part of this study. Such studies were performed by Vilans¹ and will be described in separate reports.

1.3 Objectives

The objectives of this study were:

- to evaluate the completeness and quality of the supplied documentation;
- to evaluate whether the manufacturers have considered untrained use of OTC medical devices;
- to evaluate the suitability of the user information supplied with OTC medical devices for lay users.

¹ <http://www.vilans.nl/>

2 Methods

2.1 Selection of products

In order to investigate the extent to which manufacturers have considered the use of OTC products by lay users, it was decided to select two OTC products, instead of trying to cover the whole range of OTC products. In consultation with the IGZ, two groups of OTC medical devices, relatively new to the consumer market, were selected:

- IR thermometers (ear and forehead thermometers or a combination of both)
- Wound care products (hydrocolloid wound dressings, wound sprays)

Both groups of devices are widely available to consumers and represent different risk classes. IR thermometers are classified as Class IIa under classification rule 10 of the MDD, while wound care products may be in Class I, IIa or IIb under rule 4 (MEDDEV 2.4/1).

An overview of products on the Dutch market was drawn up for both groups by searching the internet and visiting points of sale. From this product overview, a representative sample of products (different brands, different types) was purchased in drugstores and electronic goods stores.

2.2 Requests for documentation

The Dutch manufacturers or distributors as mentioned on the packaging, label or manual of the purchased products were requested by the IGZ to send a set of documentation (hereafter: the file) to the RIVM, consisting of:

- risk analysis
- instructions for use (Dutch version and, if available, English version)
- label and packaging²
- post-market surveillance (PMS) procedure
- if available: results of studies carried out with lay users

The latter part of documentation is not a legal requirement, but was requested to be able to assess whether manufacturers have evaluated the use of their product by lay users in actual practice.

If available, the English version of the instructions for use was used to verify Dutch translations.

Manufacturers received a first request (autumn 2006) and a reminder was sent by the IGZ after one month. If, following these actions, files were still incomplete, the IGZ sent a second reminder (first quarter 2007).

2.3 Assessment of files

For the assessment of the files, checklists have been drawn up. These checklists contained items for the assessment of comprehensiveness of risk analyses, instructions for use, and labelling as well as some issues with regard to PMS and test reports.

In particular items were included to evaluate whether manufacturers have considered the use of the device by lay users (e.g. factors in the home environment, knowledge level of lay users, and readability of the instructions for use). Specific risks of these products have been surveyed using literature databases, adverse events reporting systems (ECRI³, FDA⁴), warnings in the instructions for use, and interviews with experts.

Another point of attention was the compliance with legal requirements, such as presence of name and address of the manufacturer on the packaging or label, use of symbols, and information on the intended use (MDD).

Finally, the coherence of the risk analyses and the instructions for use was compared. This gives important information about the way a company deals with risks. Reducing risks throughout the lifetime of a medical device is a crucial principle in the MDD.

² The packaging was either a cardboard box or a display carton. The label has been considered as the information on the device itself.

³ Emergency Care Research Institute (ECRI), <http://www.ecri.org/>

⁴ US Food and Drug Administration (FDA), <http://www.fda.gov/>

Each product file has been assessed independently by two assessors. To achieve a consistent assessment, a guidance document has been drawn up, giving guidance for the interpretation of the items in the checklists. Diverging assessments were discussed to reach consensus and, if needed, the guidance was adapted accordingly and the previous files were re-assessed on that specific item. Data have been entered in a database using SPSS-software (SPSS Inc., Chicago, IL, USA).

The results are presented using randomly assigned file numbers, ensuring that results can not be traced back to a specific product.

3 IR thermometers

3.1 Introduction

In case of disease, body temperature often shows a deviation from normal values. Therefore, measurements of body temperature are used in the diagnosis and monitoring of diseases. A measurement using a 'mercury-in-glass'-thermometer or, nowadays, an electronic pen thermometer takes one or several minutes. The thermometer is inserted rectally, orally or axillary, which can be uncomfortable for patient and troublesome for the caregiver. IR thermometers measure the temperature of the tympanic membrane or of the forehead by measuring the IR radiation that is emitted as a function of temperature. Measurements with such thermometers take only a few seconds and take place in the ear canal or on the forehead skin which is less inconvenient for the patient. Therefore, IR ear thermometers (or 'tympanic thermometers') are widely used nowadays in hospitals (pers. comm. SMPE/e) and IR forehead thermometers have been used in screening for infectious diseases like SARS (Ng et al., 2005; Pusnik et al., 2004). The reliability of IR thermometers has been questioned (van Berkel et al., 1998; Craig et al., 2002; Dodd et al., 2006; ECRI, 1998; Lanham et al., 1999; MHRA, 2003; Riddell & Epprich, 2001; Suleman et al., 2002). Temperatures measured are often too low, which can result in a fever not being detected. From a technical point of view, most IR-thermometers are quite fail-safe. A search in the US Food and Drug Administration (FDA) MAUDE database for device failures in the period 1-1-2003 through 29-9-2006 (product code FLL: clinical electronic thermometers) resulted in only four reported problems with IR thermometers (failure of probe cover switch, calibration problems, too high temperatures, too low temperatures). There is no information on the extent of possible underreporting. However, independent of technical failure, the results of measurements of IR thermometers are influenced by external and physiological factors and by the way measurements are performed. This may result in displayed temperatures deviating from the actual body temperature. Factors influencing the result of IR temperature measurements are listed below.

Factors influencing the result of IR temperature measurement (applicable to IR ear and forehead thermometers):

- local environmental conditions : ambient temperature and humidity (ECRI, 1998; MHRA, 2005, Nimah et al., 2006);
- drift (Pusnik et al., 2004, Pusnik & Drnovsek, 2005): the reading increases when the thermometer warms itself (caused by multiple readings during a short period of time and/or holding the thermometer in the warm hand of the user);
- the cleanliness of the lens and, if applicable, the 'lens filter' or 'probe cover' (MHRA, 2003);
- time between cleaning and measuring: cleaning may influence the temperature of the thermometer or there may be a residue of e.g. alcohol and this may influence the measurement result (user manuals);
- the temperature measured: the precision of the thermometer is given for a range of temperatures and may be different outside this range (EN 12470-5).

Additional factors influencing the result of IR ear temperature measurements:

- the filtering effects of the probe cover (MHRA, 2005; Pusnik & Drnovsek, 2005): a probe cover is a relatively strong filter for radiation. Temperature readings without cover are substantially higher (+/- 1°C). It is important to use only the original probe covers for which the manufacturer must ensure constant and stable spectral characteristics;
- setting of the probe cover (Pusnik & Drnovsek, 2005): a larger deviation and a lower reading is obtained when there is an air gap between probe and cover, due to gentle setting;
- the position of the sensor due to differences in the emissivity and temperature of tympanic membrane and the wall of the ear canal (MHRA, 2005; Pusnik et al., 2004; Pusnik & Drnovsek, 2005): tympanic temperature differs from the average ear canal temperature. Because an ear thermometer has a large viewing angle, it inevitably measures also some portion of the ear canal. Depending on the position of the thermometer this portion can be smaller or larger (MHRA, 2003; Pusnik & Drnovsek, 2005);

- ear anatomy, e.g. long, narrow, curvy ear canal (ECRI, 1998); this impedes a good ‘view’ of the tympanic membrane, e.g. in young children;
- obstructions in the ear canal, e.g. ear wax (MHRA, 2005; Pusnik et al., 2004): this impedes a good ‘view’ of the tympanic membrane;
- ear lying on pillow or mattress just before measuring (MHRA, 2005): an ear that was lying on a pillow just before measuring has a higher temperature (Sievert et al., 1999);
- left or right ear (MHRA, 2005; Pusnik et al., 2004): there may be differences and measurements of the same ear should be compared with each other;
- otitis media: an ear affected by otitis media will have a higher temperature (Sievert et al., 1999; Simon, 1996).

The influence of ear tubes is unknown, but this could theoretically result in a lower temperature (pers. comm. SMPE/e).

Additional factors influencing the result of IR forehead temperature measurements (MHRA, 2005):

- distance to the skin;
- covering the forehead with make-up, hair, etc.;
- wearing head covers just before measuring, e.g. a hat or scarf;
- cooling agents, like cold compresses, on the forehead just before measuring;
- perspiration of the forehead;
- coming from a warm or cold environment just before measurement;
- lamp light or sunlight on the forehead;
- moving air, e.g. air-conditioning or draught;

No information was found on the influence of skin colour and of scars or sunburn.

In recent years IR thermometers have appeared on the consumer market and have been promoted increasingly for self use. The use of most IR thermometers is more complex than application of digital contact thermometers (e.g. because of self test, memory function, use of symbols in the display and positioning). Therefore, appropriate instructions are indispensable. Referring to the factors mentioned above, warnings on safe application and the reliability of the obtained temperature values are necessary.

3.2 Results

3.2.1 Selected products and completeness of files

An overview of the selected IR-thermometers is presented in Table 1. Figure 1 depicts one of the IR thermometers evaluated in this study. The completeness of files is given in Table 2. For the completeness of files *per respondent*: see Appendix II.

Figure 1: One of the evaluated IR thermometers



Only one respondent, a manufacturer, sent in a PMS procedure. Only manufacturers are legally required to have a PMS procedure. Of the seven respondents (one respondent sent the documentation of two thermometers) three were manufacturers and three were distributors. The status of one respondent was unknown. Only four risk analyses were received.

No results from studies carried out with lay users were received.

Table 1. Selected IR-thermometers (n=8)

Selected IR-thermometers	Number
Ear thermometer	5
Forehead thermometer	2
Combined thermometer (ear/forehead)	1

Table 2. Completeness of files (n=8)

Documentation	Number of documents
Risk analysis	4 ^{a,b}
Instructions for use	8
Packaging	8
Label on device	8 ^c
PMS procedure	1
Vigilance procedure (not requested by the IGZ)	1
Studies carried out with lay users	0

a. In two files a risk management procedure was included instead of the results of the risk analysis. Two other files contained no risk document at all.

b. Two risk analyses were received for ear thermometers and two for forehead thermometers.

c. One thermometer has only the name of the manufacturer as a 'label'.

The complete results of the file assessments are presented in Appendix III. Below, a description of the main outcomes is given.

3.2.2 Assessment of risk analysis

Risk analyses (n=4) were assessed on mentioning risks with regard to '*design and specifications*', '*use errors*', '*technical failures*' and '*errors in storage, maintenance and calibration*'. In Table 3 examples of the points of attention for the risk analyses are presented.

Table 3. Examples of points of assessment for the risk analysis of IR-thermometers

Type of error	Examples
<i>Design and specification errors</i>	Inaccurate readings/low accuracy, wrong temperature calibration by manufacturer, use of performance and/or safety standards
<i>Use errors</i>	Operating outside prescribed environmental temperature, incorrect position of the thermometer, not removing ear wax or head covering respectively, influence of exercise/sleep/bathing, intervals between two measurements too short, cross infection, incorrect interpretation of displayed temperature by user
<i>Technical failures</i>	Failure of the IR sensor, electromagnetic interference, harmful effects of dropping on accuracy, effects of penetration of water or other fluids
<i>Errors in storage, maintenance and calibration</i>	Storage conditions outside range specified by manufacturer, low battery, incorrect battery placement, incorrect cleaning

3.2.2.1 *Design and specifications*

In all four risk analyses received, the risk of inaccurate readings/low accuracy was considered. Due to inaccurate temperature measurements the presence of fever may not be detected, resulting in no or delayed consultation of a doctor.

Errors in temperature calibration by the manufacturer were mentioned in three risk analyses. Also the application of performance and/or safety standards (e.g. NEN-EN 12470-5, NEN-EN IEC 60601-1, NEN-EN-IEC 60601-1-2) was cited three times.

The influence of low power supply, of environmental conditions (ambient temperature, humidity) and of the filtering effects of e.g. probe covers was each mentioned only once.

The following risks were described in none of the four risk analyses received;

- effects of differences in emissivity of the measured surface (see 3.1.);
- influence of differences in age on measurement (neonates etc.);
- the measured temperature is outside the range specified by the manufacturer;
- effects of the temperature of the thermometer/drift (see 3.1.);

3.2.2.2 *Use errors*

The risk of 'cross infection' (due to insufficient cleaning of the thermometer or improper use of lens covers) was mentioned in all four risk analyses. Four items ('use by unskilled users', 'insufficient user instruction', 'incorrect readings or interpretation', 'incorrect positioning') were addressed in half (2 out of 4) of the risk analyses, and 'operating outside prescribed environmental temperature' was considered once. Other aspects were not described, for example the risk that a user maintains an insufficient time interval between two measurements, after sleep or after cleansing.

Most use errors and conditions specific to ear thermometers, i.e. 'manipulation of the probe', 'influence of obstructions in the ear canal', 'influence of lying of the ear on a pillow just before measuring' and 'differences between left and right ear in repeated measurements' were not described in any of the relevant risk analyses.

Likewise, no aspects specific to forehead thermometers were addressed in the risk analyses concerned: e.g. 'forehead perspiring', 'coming from outside just before measurement', 'lamplight or sunlight on the forehead'.

3.2.2.3 *Technical failures*

Two risk analyses described most issues (5 out of 7), and the other two documents consider only two aspects ('failure of sensor/probe' and 'effects of dropping on accuracy'). One risk ('the penetration of water or other fluids') was never mentioned.

3.2.2.4 *Storage, maintenance and calibration*

One risk analysis mentioned three items out of five; the other documents mentioned only one item. 'Storage conditions' and 'removal of battery before storage' were mentioned twice, 'low battery' and 'incorrect cleaning' only once. None of the manufacturers considered the risk of 'incorrect battery replacement'.

3.2.2.5 *Set up of risk analysis*

All four risk analyses received referred to the international standard for the application of risk management to medical devices - NEN-EN-ISO 14971 and included mentioning, estimating and reducing of possible risks. Two documents (one of an ear thermometer, one of a forehead thermometer, apparently of the same producer) were identical 2-page-documents called "FMEA to users". The other two were more extensive, and were similar in the arrangement in chapters 'characteristics that could affect safety', 'possible hazards', and 'analysis', but they contained remarks that raise questions, like:

- "No one can control or influence the use of the medical device",
- "Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds?" Answer: "No",
- " "Replace or clean probe cover after each use" should be set out in the user's manual to avoid the possibility of re-use of the probe cover".

3.2.3 Assessment of user information

The checklist for user information was largely based on the European standard for IR-ear thermometers (NEN-EN 12470-5). For IR forehead thermometers no separate European standard exists.

3.2.3.1 *User manual*

Design and specifications

Information on the intended body site (ear, forehead), the local environmental conditions required for measurement (ambient temperature, humidity) and on the self test performed by the device was given in all user manuals. Most manuals stated the name of the manufacturer, the full address of manufacturer/European representative, CE mark, the code of the notified body, the measuring range, the correct sensor position, the displayed temperature and some safety precautions. In five (out of 8) manuals remarks were made about the minimum time between subsequent measurements to prevent drift.

Less attention was paid to:

- Influence of age on measurement (n=4). For new-born, young children it may be advisable to measure multiple times to get a valid/accurate measurement;
- the upper limit of normal temperature (n=3);

According to the standard NEN-EN 12470-5 for IR ear thermometers, values of site offsets to adjust displayed temperature to a specific body site should be specified if applicable. The manuals contain no such information, which might in fact be too complicated for lay users. Nevertheless it is often claimed that body temperature is displayed while ear temperature is measured. In one case some explanation is given on differences in temperature between body sites, and the advice is given to determine personal ranges of normal temperatures. However, this may not be an easy task for a lay user.

In manuals of forehead thermometers some explanation was given on differences between body sites and the influence of external outside influences. The users were advised to consult a doctor when they feel the condition of the patient does not correspond with the measured temperature, or to repeat the measurement with a thermometer of another type in case of doubt.

The specifications related to temperature measurement, as mentioned in the user manuals, are shown in Table 4.

Table 4. Selected IR-thermometers (n=8)

Thermometer product id.	Error (°C)	Repeatability (°C)	Displayed temperature (°C)	Ambient temperature (°C)
1	± 0,2 at 36-39 ± 0,3 outside this range		34 - 42.2	10-40
2	± 0,2 at 36-39 (lab.)		34.0- 42.2	16-40
3	± 0,2 at 32-42,2		0 - 100	5-40
4	± 0,3 (labo.)			10-50
5	± 0,2 at 35.5-42.0 ± 0,3 outside this range	± 0,14	34 - 42.2	10-40
6	± 0,2 at 35.5-42.0		34 - 44.0	16-35
7	± 0,2 at 35.5-42.0 (lab.) ± 0,3 outside this range		32 - 42.9	16-40
8	± 0,2 at 35.5-42.0	± 0,1	10 - 50	16-40
NEN-EN-ISO12470-5	± 0,2 at 35.5-42 ± 0,3 outside this range	± 0,3	35.5- 42.0	16-35

For two ear thermometers the requirements of EN 12470-5 are met. The two forehead thermometers do not meet these specifications for ear thermometers.

Information on the manufacturer (both name and address) lacked in one manual. A name and the P.O. Box were found on the packaging of this thermometer, yet no information was given on the status of this company. Six manuals referred to performance standards. A reference to the standard for IR ear

thermometers NEN-EN 12470-5 was made three times. If no reference to the standard NEN-EN 12470-5 (n=5) was made, it was checked whether alternative standards were mentioned: reference to the US Standard Specification for IR thermometers ASTM 1965-98 was made three times. These three included the two forehead thermometers, which are not covered by NEN-EN 12470-5. In the user information of one ear and a combined thermometer, no reference to performance standards was made.

Use errors

In general, manuals described different sets of warnings to prevent use errors. The instructions to prevent use errors were described insufficiently; especially warnings with regard to forehead thermometers were poor.

Examples of warnings/instructions to prevent inaccurate measurements caused by use errors that were included in the user manuals of ear thermometers are given below⁵:

- check if the ear canal is dry (n=0);
- check if the ear canal is clean (n=6);
- check if the thermometer lens/probe is clean (n=4);
- do not exercise before/during measurement (n=1);
- do not talk during measurement (n=0);
- do not measure the ear that has just been lying on a pillow/mattress (n=3);
- do not take a reading within 30 minutes of bathing/showering/swimming (n=2);
- compare measurements of the same ear (n=4);
- do not measure just after the application of ear drops (n=1).

It is noticeable that only the instruction to check if the ear canal is clean was mentioned in all the manuals for ear thermometers. There was no manual which contained almost all of the warnings and instructions (see appendix III). Although four thermometers required probe covers, in two manuals the instructions how to apply probe covers were insufficient or absent. Furthermore, a third manual was inconsistent with regard to the probe covers for single use: whereas the probe covers for this thermometer were stated to be for single use, cleaning instructions for the probe covers were given.

The warnings/instructions with regard to forehead thermometers (3 manuals) were poorly mentioned in the manuals⁶:

- avoid moving air such as air-conditioning and draught (n=0);
- the forehead should not be perspiring (n=2);
- the forehead should not be covered with make-up (n=1);
- avoid measuring skin that is close to a lamp or exposed to sunlight (n=0);
- do not take readings shortly after exercise (n=2);
- do not take readings shortly after bathing/showering (n=1);
- do not take readings shortly after wearing e.g. scarf, hat, cap etc. (n=0);
- do not take readings shortly after having a cold compress on the head (n=0);
- do not take readings on forehead of baby shortly after feeding a baby (n=1);
- move away hair from forehead skin (n=1).

Technical failures

Moderate attention was paid to technical failures. All manuals warned to avoid extreme circumstances during measurement. The warning: 'prevent water or other fluids' was once not written out, but a symbol was displayed on the packaging of this thermometer. Except for two manuals, a trouble shooting guide was given in the instructions for use. Only half of the manuals contained a warning for mechanical shocks, such as dropping. An address for repair, service and calibration was lacking twice.

Storage, maintenance and calibration

⁵ One thermometer can be used for the ear and forehead, giving a total of six assessments of instructions for use of ear thermometers

⁶ One thermometer can be used for the ear and forehead, giving a total of three assessments of instructions for use of forehead thermometers

Information on storage conditions (n=8), cleaning instructions (n=8), disposal of the device (n=8) and battery replacement (n=7) was described well. Almost all manuals contained information on how to obtain maintenance or calibration service (n=7), although in one of these only the procedure was mentioned and no address.

According to four manuals or risk analyses calibration of the thermometer was not necessary (scored NA). Two times it did not appear from either the risk analysis or the instructions for use whether calibration is necessary or not (scored “no”). In one case biennial technical inspection was recommended for professional users with a reference to detailed information on services. In another case it was stated that recalibration is necessary every two years, but in this case no information was given about the way to perform or obtain recalibration.

The table in Appendix V indicates that for five thermometers the number of items not addressed in the user information is between 10 and 15. For two ear thermometers and a combined thermometer the number of items missing ranges from 22 to 24.

3.2.3.2 Readability

All manuals were written in the Dutch language, but the phrasing was not always clear. Three of eight manuals contained passages that were badly translated and therefore ‘correct usage’ was scored as ‘no’. In fact in most manuals some poor phrasing could be found (see textbox 1).

Textbox 1: Examples of poor phrasing in the Dutch user manual:

‘actuele tijd’, ‘leveringsomvang’, ‘moet de sensorafdekking opgestoken zijn’, ‘zelfdiagnose functie’, ‘omgevingstemperatuur compensatie technologie’, ‘stabiel resultaat zonder warmte-interferentie’, ‘alcoholstokje’, ‘scansequenties’, ‘speciale meetmodus’, ‘registratiesequenties’, ‘een geregelde modus’, ‘bedrijfsomgeving’, ‘sondepunt’

In addition, the character size used in the manuals was often too small (font size smaller than 9 points Times new roman). This restricts the readability, especially for elderly.

Terms (probe, probe cover, battery cover etc.) were often (n=7) explained by means of a drawing with a glossary. Symbols on the packaging or the display were explained (n=7) in the manual.

3.2.3.3 Labelling

Except for one thermometer, the brand or type, the CE mark and the code of the Notified Body appeared on the labels of the selected IR-thermometers.

The name of the manufacturer appeared on six labels. On two labels the name of the manufacturer was absent but could be found on the packaging of these thermometers. The address of the manufacturer was on none of the labels.

The labelling of most products referred to the instructions for use with the ‘read instructions for use’-symbol according to the standard for symbols NEN-EN 980 (n=6).

One label also contained a warning, but not in Dutch (in English/German: “Use with probe covers only! / Messen nur mit Sensor-Schutzkappe!”).

Information on the intended body site (e.g. intended to measure in ear or on forehead), whether probe covers have to be used, the year and month of manufacture were not commonly (n=1) given on the label. The symbol ‘°C’ or ‘°F’ was always shown on the display.

3.2.3.4 Packaging

All packages stated the CE-mark as well as the Notified Body code on the packaging and also the body site (ear, forehead) was always mentioned.

On one packaging, the name of the manufacturer was absent. Information on this manufacturer (name and address) did appear in the instructions for use of the thermometer, as well as on the label (name only).

Another packaging did not mention the brand and type of the device.

Two packages of ear-thermometers contained no information on the use of probe covers, although these are needed for use.

The displayed temperature (e.g. core temperature), a reference to the instructions for use and the full address of the manufacturer / European representative were each given on half of the packages (n=4). The year and month of manufacture (and of first calibration if different) was given on none of the packages. One of the manufacturers included a very short instruction for use as a sticker inside of the plastic protection-box. However, this information was in English, not in Dutch.

3.2.4 Coherence between risk analysis and manual

The coherence between the risk analyses and user manuals was evaluated for four products for which the risk analyses were received (see Table 5).

Table 5. Reciprocity between risk analysis and user manual

Thermometer product id. ^a	References to user manual in risk analysis	Thereof mentioned in user manual	Additional points of attention in user manual
1	16	11	0
2	4	3	13
3	4	3	13
4	6	4	19

a. Four files contain a risk analyses. Therefore, reciprocity has only been assessed for four files (number 1 to 4)

For all products it was found that not all risks to be addressed in the user manual according to the risk analysis were actually addressed in the manual. Adjoining to this finding in three out of four user manuals a considerable number of aspects was included that needs attention to obtain good measuring results, but had not been mentioned in the risk analysis of the device.

3.2.5 PMS

The only PMS procedure received did not describe active forms of surveillance, such as customer surveys. Instead, the packaging of the thermometer contained a questionnaire allowing the user to give his opinion about e.g. the user manual.

3.2.6 Test reports lay users

No test reports of studies among lay-users were received. However, two respondents did send in documents for professional users. One document was a protocol and the second document was an incomplete test report.

3.3 Discussion

3.3.1 General

The advantages of IR ear thermometry - rapidity, ease of use, patient comfort, cleanliness, safety - have brought about an easy introduction in hospitals. The ease of use is also a strong sales argument for the consumer market. At home a lack of attention, shortcomings in understanding, or simply the loss of the manual may result in improper application and incorrect results. The introduction of forehead thermometers has progressed less far until now, but these devices have comparable advantages of ease of use and risks of incorrect use.

The main types of IR clinical thermometers on the Dutch consumer market were covered. During the course of the investigation a “talking” IR thermometer was introduced on the market, which was too late to include the product in this investigation.

On the consumer market, more ear thermometers than forehead thermometers or combined thermometers are available at this moment. Some manufacturers are established medical device manufacturers, but not all manufacturers may be familiar with European medical device regulation. This might explain that only half of the respondents could present a risk analysis and only one PMS procedure was received. Studies with lay users were not received and are not required in the MDD. However they could give useful information for manufacturers of consumer medical devices, especially if the type of product is recently

introduced into the consumer market. In a report of Vilans, the results will be described of a test in a consumer panel of the thermometers involved in our study.

3.3.2 Risk analysis

In general the risk analysis is an item which needs to be improved. In most risk analyses received, precision and calibration of the devices as well as the application of performance and safety standards is addressed. However, according to the literature, there are many external and physical conditions that may influence the results of IR temperature measurement. Little mention is made of these conditions, neither by making reference to user instructions, nor by considering them as possible use errors. Nevertheless many of these aspects appear in the user instructions. Two risk analyses describe technical failures rather well; two other documents mention only a few issues. Some quite conceivable practical events like 'mechanical shock/dropping' and 'penetration of fluids' are not addressed in any document. Aspects of storage and maintenance are dealt with only partially in risk analyses.

All risk analyses received referred to the risk management standard NEN-EN-ISO 14971, but there were major differences in extensiveness and the way these documents were set up.

3.3.3 User information

In the manuals most items concerning 'design and specifications' are addressed. However, some technical specifications as required in NEN-EN 12470-5 for IR ear thermometers (e.g. physiological site offsets and algorithms dealing with temperature differences between body sites) could not be found in the manuals. Yet, according to the ear thermometer manuals studied, body or core temperature is presented, whereas ear temperature is measured. Information on offsets and algorithms is possibly considered too complicated for lay users. For a correct interpretation of results some manuals present background information on temperature differences between body sites.

The specifications related to temperature measurement (error with the relevant temperature range, repeatability, displayed temperature, ambient temperature) were mentioned completely and were in according to NEN-EN-ISO 12470-5 in the user manual of only two ear thermometers. For forehead thermometers no European standard mentioning such specifications is available at moment. In fact complete specifications may be too complex for lay users.

For IR ear thermometers used in hospital a calibration mode must be accessible and these thermometers are calibrated regularly (e.g. once a year (pers. comm. SMPE/e). In most cases (re)-calibration seems not to be considered necessary for self use by the manufacturers.

The above mentioned standard NEN-EN 12470-5 does not mention lay use in its scope and seems to be written for professional use.

The manufacturers of the forehead thermometers do realize that measurement results of these devices can differ from core temperature in many circumstances, and warn the user to consult a doctor or to repeat the measurement with a device of another type in case of doubt. This leaves the impression that the value of IR forehead temperature measurement is limited.

Although considerable attention is paid in manuals to external and physical circumstances that influence measurement results and to possible use errors, on average still a substantial part of the issues in the checklist is not addressed. Correct positioning of ear thermometers is addressed in most manuals, but lay users have no professional lighting at their disposal to see the ear drum and to control whether the ear canal is dry, clean and without earwax or inflammation. Positioning of a thermometer in the ear of a little child can be problematic because the ear canal may be very narrow and curvy. Inflammation of the ear (otitis), which is a common condition in children, influences measurement results. Users are often instructed to clean the ear canal from earwax, but it is not described how this can be done safely. The effects of ear tubes on ear thermometry and of the skin colour, sunburn or scars on forehead thermometry are not mentioned. The influence of ear tubes could theoretically result in a lower temperature (pers. comm. SMPE/e).

Only half of the manuals warn for dropping the device, which is a conceivable event. It is possible that the self test is expected to diagnose every malfunction, such a diagnosis resulting in the impossibility to perform any more measurements.

Storage and maintenance are described well in the manuals. Recalibration is considered not necessary for self use except for one thermometer. According to literature regular recalibration of IR thermometers is necessary for professional use (MHRA 2005, Pusnik et al. 2004, Pusnik and Drnovsek 2005), and NEN-EN 12470-5 requires the accessibility of a calibration mode. From the documentation received, it is not clear for what reasons this is not necessary for consumer devices. It is striking that the one manual mentioning the necessity of recalibration every two years, does not include any information on how to obtain recalibration service.

IR sensing thermometers are Class IIa devices according to the classification rules of the MDD (MHRA, 2005). The standard: NEN-EN 12470-5 applies for IR ear thermometers. For two of the five ear thermometers it is not clear whether this standard was not applied or just not mentioned in the user information. Currently (2007) no specific international performance standards have been published for IR forehead thermometers. The US document ASTM 1965-98 includes testing procedures for skin thermometers which some manufacturers may consider applicable to their product (MHRA, 2005). In the user information of one ear and the two forehead thermometers, reference was made to this standard.

Instructions for use were comprehensible except for some poor phrasing. Readability was often compromised by small character size. Because IR thermometers are more complex products than digital pen thermometers and because a multitude of circumstances may influence the measuring result, user manuals have to be very clear and well readable.

3.3.4 Coherence

It is striking that possible use errors and external and physical conditions, that may influence measuring results, are hardly addressed in risk analyses but are nevertheless found in user manuals. An explanation could be that risk analyses are drawn up by producers who are hardly familiar with the application and performance of the devices in daily practice. Inclusion of such issues in the manuals by manufacturers might be based on experience or literature study rather than on the risk analysis of the device.

3.3.5 PMS

The only PMS procedure received lacked a description of active forms of surveillance. This finding is in line with the results of former studies (Roszek 2005, Roszek 2006).

3.3.6 Test reports lay users

No results of tests done with lay users were received. Two respondents did send in documents for tests with professional users, but no test results. At this moment no specific legal requirement (MDD) exists with regard to performing studies with lay users, however sound risk management could well require such studies. Because IR thermometers are rather complex and relatively new to the consumer market, tests done with lay users could generate data on whether the design and the information supplied are sufficient to allow safe use by first time lay users.

3.4 **Conclusions**

- According to literature use errors, physiological and environmental factors may cause erroneous measurement results: e.g. due to incorrect positioning, narrow curvy ear canal in children, ear wax or forehead coverage, exercise, sleep, draught or air conditioning, incorrect cleaning
- All files contained user information but a risk analysis was received from only half of the respondents. No studies with lay users were submitted.
- The risk analyses received referred to the current risk management standard;
- In risk analysis documents little mention is made in the design and specifications part of external and physical factors influencing the measuring results and little attention is paid to use errors. Therefore the quality is insufficient.

- Although user information was more complete than risk analysis documents, on average only about half (ear thermometers) and about a quarter (forehead thermometers) of the issues checked was addressed. Improvements are therefore considered necessary.
- User manuals were not sufficient in warnings or instructions to prevent inaccurate measurements.
- Information on storage and maintenance was given in all manuals.
- Readability of user manuals was often compromised by small character size and poor phrasing.
- Labelling and packaging together contained most of the information required in the MDD.
- Only one PMS procedure was received. The quality of this document was insufficient, because it lacked forms of active surveillance.

4 Wound care products

4.1 Introduction

The treatment of wounds should be selected based on wound characteristics. If the surface area of the wound is large, or if the wound is deep, a physician should be consulted. If the wound is a minor laceration or abrasion (e.g. friction blister, minor cuts), patients can treat the wound with an OTC product themselves (Casper, 2006).

Two types of products, relatively new to the consumer market, have been included in this survey:

- hydrocolloids wound dressings
- wound sprays

After first being introduced in the professional environment, these products are now available to consumers in drugstores and pharmacies.

4.1.1 Hydrocolloids

Hydrocolloid dressings create a moist wound environment supporting the wound healing process. The dressings interact with wound exudates to form a soft gel (Leaper et al, 2002). Typical absorptive, gel forming ingredients are carboxymethylcellulose, pectin and gelatin. In many products, these are combined with elastomers and adhesives and applied to a carrier, usually polyurethane foam or film, to form an absorbent, self adhesive, waterproof wafer (Thomas, 1997, Heenan 1998). Initially, the dressings are impermeable to water vapour, but as the gelling process takes place, the dressing becomes progressively more permeable. The loss of water through the dressing enhances the ability of the product to cope with exudate production (Heenan, 1998). For a good effect, it is important that the dressing forms an adequate seal over the wound.

Because they are occlusive, hydrocolloid dressings do not allow water, oxygen, or bacteria into the wounds. This may help angiogenesis and granulation (Hess, 2000). However, if a wound contains anaerobic micro-organisms, the use of a hydrocolloid – or other occlusive dressing – creates a favourable environment for these micro-organisms. If these micro-organisms are particularly virulent or pathogenic, the use of a hydrocolloid can be dangerous, particularly if left for a longer period of time. Therefore, these dressings are not recommended for prolonged use with infected wounds (Finnie, 2002).

Some of these dressings may cause sensitivity reactions due to components, mainly the adhesives and gelatine (Finnie, 2002).

Hydrocolloids are applied in the treatment of clean, granulating, superficial wounds with medium to low exudates (Hageman & Klaucke, 2005). Some products are specifically intended for the treatment of blisters.

Hydrocolloids sheets are available in various thicknesses and in pre-cut shapes for body areas such as the sacrum, elbows and heels. Some sheet hydrocolloids are opaque, making wound assessment difficult, others are transparent (Hess, 2000). Consumer hydrocolloids are sold as gel strips. These packages contain several plasters that are often individually wrapped.

Hydrocolloids require changing every three to five days, depending on the exudates level and the type of wound (Finnie, 2002; Heenan, 1998).

When a hydrocolloid dressing has a high absorption capacity, it may adhere to the wound and may damage the wound bed. On the other hand, low absorption capacity may cause maceration of the tissue surrounding the wound. Another point is the adherence of the bandage. If this adheres too strong, it may damage the skin upon removal, whereas low adherence can cause early detachment of the dressing.

Under certain circumstances, hydrocolloids should be used with caution or a physician should be consulted (Finnie, 2002; Heenan, 1998; Hess, 2000). These include:

- infected wounds: characterized by e.g. redness, pain, swelling;
- heavily exudating wounds (the hydrocolloid mechanism fails);
- users with diabetes (increased risk of sensory loss, ulcers, infection or delayed healing time);
- immunodeficiency.

In addition, if a patient is allergic to the ingredients of the dressing, it should not be used.

4.1.2 Wound sprays

Bandages are also available as sprays. Most sprays protect the wound ('bandage spray'), while some sprays are intended to stem bleeding ('stops bleeding spray').

The stops bleeding spray is intended for the topical treatment of bleeding from surface skin injuries such as cuts, abrasions and lacerations. When sprayed, the liquid component of the content evaporates leaving a thin layer of powder on the skin that forms a soft gel-like layer over the wound to stop bleeding.

The bandage spray is indicated for minor cuts and scrapes that are clean and dry. The bleeding must be stopped before spray application. The spray leaves a thin transparent film on the affected area and forms a mechanical barrier protecting the wound. This film is breathable and seals out water, dirt and germs. It does not provide a moist environment like the hydrocolloid dressings. During wound healing the polymer coating sloughs off naturally. The bandage spray should not be used on infected wounds, and contact with eye, mouth or mucosa must be prevented.

Both types of wound sprays appear in pressurised spray cans, and contain up to 40 applications.

4.2 Results

4.2.1 Selected products and completeness of files

The number and type of the selected wound care products is presented in Table 6. Figure 2 depicts several wound care products evaluated in this study. The completeness of files is given in Table 7. For the completeness of files *per respondent*: see Appendix II.

Table 6. Selected wound care products (n=8).

Selected Wound care products	Number
Hydrocolloid dressings	5
Wound sprays	3 ^a

a. Two bandage sprays and one stops bleeding spray.

Figure 2: Several evaluated wound care products



Table 7. Completeness of files (n=8).

Documentation	Number
Risk analysis	6
Instructions for use	8
Packaging	7 ^a
Label ^b	3
PMS procedure	7 ^c
Vigilance procedure ^d	5
Studies carried out with lay users	1 ^e

a. One wound spray had no separate packaging.

b. Only applicable to the wound sprays (n=3).

c. One respondent sent the results of the PMS, but without the PMS procedure (scored absent).

d. Not requested.

e. One additional study was received after closure of the investigation and was therefore not included in our investigation.

4.2.2 Assessment of risk analysis

Six risk analyses were received; four for hydrocolloid dressings and two for wound sprays. Risks regarding ‘*design and specifications*’, ‘*use errors*’, and ‘*errors in storage*’ in the analyses were assessed. Examples of the assessed items are presented in Table 8.

Table 8. Examples of points of attention for the risk analysis of wound care products

Type of risk	Examples
<i>Design and specification</i>	Skin irritation by components of product, expired product, microbiological contamination during manufacturing process, product which is labelled sterile may not be sterile, interaction with substances (oil, cream on skin)
<i>Use errors</i>	Use on infected skin, use on dirty skin, wrong product used, dressing removed too late (hydrocolloids)
<i>Storage</i>	Inadequate storage (too warm, too humid, keeping in sunlight) may cause changes in product

(Heenan, 1998; Hess, 2000, risk analyses, personal communication)

The full assessment of the risk analysis is presented in appendix IV.

4.2.2.1 *Design and specifications*

The risk concerning a non-sterile product was mentioned for the one product for which it was applicable. The risks concerning ‘skin irritation’ and ‘expired product’ were considered in all but one of the analyses. Risks missing in two out of six risk analyses were: the risk that a product does not meet the specifications, risk of interaction of the product with other substances (e.g. oil, cream) and risk of long-term use. The risks for “damage of product” and “insufficient user instructions” were not mentioned in three out of six risk analyses.

The risk of an open wrapper was considered in all four risk analyses of the hydrocolloid dressings. The risk of microbiological contamination during production and packaging was considered in half of the risk analyses (2/4), whereas other risks concerning design and specifications of hydrocolloids were only missing for one product.

4.2.2.2 *Use errors*

Risks related to use errors are divided into general errors and product specific use errors for the hydrocolloid dressings and wound sprays separately.

The risk of ‘use on deeply injured skin or heavily exudating wounds’ and the risk of ‘misunderstanding product or wrong product is used’ were often mentioned. Apart from the risk of ‘use by unskilled users’, missing twice, other general risks of wound care products were mentioned in half or less of the six risk analyses (underneath times missing between brackets):

- use on infected skin/wound/blister (n=3);
- use on severe burns (n=4);
- use on dirty skin (n=3);
- use on wet skin (n=3);
- no relevant information is available to user (n=3).

For the risks specific to hydrocolloid dressings, the risks related to damage to the skin on removal of the dressing and late removal of the dressing were each missing in one of four risk analyses.

The other risks were not addressed two or three times:

- use by patients with diabetes (n=2)
- touching the adhesive before application of dressing (n=3)
- incorrect dressing size (n=3)
- adhesive placed over wound (n=3)

For the two risk analyses received for sprays, the risks concerning contact with the eye and explosion of the device were mentioned in both analyses, whereas the other risks (e.g. spraying at mucosa, piercing or burning the spray can, keeping within reach of children) were mentioned alternately in one of the two risk analyses.

4.2.2.3 *Storage*

Inadequate storage was mentioned in four of the six risk analyses. If not stored properly, the properties of the product may deteriorate.

4.2.2.4 *Set up of risk analysis*

Three times the risk analysis referred to the current risk management standard NEN-EN-ISO 14971 and once to the preceding European standard NEN-EN 1441 (withdrawn in 2001). For the other two files, no standard was mentioned. The risk analyses referring to NEN-EN-ISO 14971 were well structured and weights were systematically ascribed to the risks. The extensiveness of the risk analyses differed between these three files. The risk analysis referring to NEN-EN 1441 was narrative and no systematic weighing of the risks was performed. One of the risk analyses for which no standard was mentioned was set up systematic. However, no weight was ascribed to the risks, although there was a ranking of risks, which was not clear. The other risk analysis for which no standard was mentioned was narrative and no weight (e.g. severity, frequency) was ascribed to the identified risk as well.

4.2.3 Assessment of user information

The full assessment of the user information is presented in appendix IV. Appendix V lists the number of items not addressed in the user information for each file.

The user information was given in several different ways. The hydrocolloid dressings were supplied in a box, on which information was given. For three of the evaluated hydrocolloids, there was an additional insert in the box.

Two out of three spray cans were supplied in a box or display carton. These additional forms of packaging contained information additional to the information supplied on the spray can. For one of the sprays, the information about the application of the spray was information that was not on the can and would be lost by discarding the outer packaging. The third spray can had no packaging.

4.2.3.1 *General*

Most general product information, such as brand, type, was given in the user information. Four items were missing from one or more files (underneath times missing between brackets, number of files=8):

- Intended use: type of wound (n=2);
- Intended use: body site (n=3);
- Full⁷ address of manufacturer or European representative (n=7);

⁷ An address was considered to be full if the complete visiting address was given. A P.O. Box only is scored as incomplete

- Notified Body (n=1).

The general instruction to clean the wound before using a wound dressing was given on all but one product. In this case, it was only mentioned to use the product on a dry skin. The instruction to apply the product on dry skin was only missing once. Other instructions were missing more often (underneath times missing between brackets, number of files=8):

- When to stop using (n=5)
- When to remove the product (n=4)

General use errors were missing in the user information of most of the products (underneath times missing between brackets, number of files=8):

- do not use if packaging is damaged (n=7);
- do not use on deeply injured skin (n=4);
- do not use on infected wounds/skin (n=4);
- do not use on severe burns (n=5);
- what to do if signs of infection or irritation occur (n=6);
- what to do if wound/blister does not start to heal (n=7);
- what to do if bleeding does not stop (n=7).

Storage conditions were mentioned in two out of five instructions of hydrocolloid products. For one these dressings, the storage instructions were given in the leaflet inside the carton, which means that the user can only be aware of the storage conditions after the first use of the product.

4.2.3.2 *Hydrocolloids*

For the five hydrocolloid dressings, the three use errors (use with diabetic diseases, do not touch adhesive and secure pouch seal is intact before use) were each mentioned in three files. There was one file, for which none of the three hydrocolloid dressing related risks were mentioned.

4.2.3.3 *Sprays*

Most of the product specific warnings were given for all three products. Only the risks related to inhalation and removal from skin were each absent in one instruction.

4.2.3.4 *Readability*

All user instructions (n=8) were in Dutch. In general, the linguistic usage was correct.

The character size used was often too small (font size smaller than 6 points Times New Roman, whereas 9 points was considered to be the minimum acceptable font size), restricting readability.

Instructions were not always clearly arranged (n=4). For example, Dutch and French instructions/warnings alternated.

It is noticeable that the term infection was explained only once. The question arises whether consumers know the signs of infection, such as redness, increased pain etc. Except for the term “P.U.R Technology” on one packaging, no difficult terms were found or an explanation of the term was given.

For five products, only symbols standardised in NEN-EN 980 were used. Once, the manufacturer explained the NEN-EN 980 symbols in the instructions for use. The three sprays had a widely used and standardised safety symbol, which was not in NEN-EN 980. This symbol was explained on all three products. Moreover, on one spray, a non-standardised symbol was used which was not explained.

4.2.4 Coherence between risk analysis and user information

Coherence between the user information and risk analysis was also evaluated (Table 9). For two files, the residual risks to be dealt with in the user information were all present in the user information, whereas for the other files, one or more residual risks to be addressed in the user information were not present in the user information. For all files the user information contained risks and warnings that were not given in the risk analysis or not marked as to be addressed in the user information.

Table 9. Coherence between user information and risk analysis

Product id. ^a	References to user information in risk analysis	Thereof mentioned in user information	Additional risks and warnings in user information
9	6	5	1
10	2	2	8
12	14	5	4
13	5	3	5
14	12	12	4
15	6	6	6 ^b

a. Six files contain a risk analysis. Therefore, reciprocity has been assessed for six files.

b. Most of these items were mentioned in the risk analysis, but no reference was made to the user information.

4.2.5 PMS

All PMS procedures received (n=7) described passive forms (i.e. customer complaint procedures). Additionally, active forms of PMS, such as customer and user surveys, were described in three out of these seven procedures.

4.2.6 Test reports lay users

With the exception of one “concept use test report” among lay users, no test reports of studies among lay users have been received before the submission deadline of this investigation. This “concept use test report” appears to be an evaluation of the redesign of the product among lay-users (measurement of the interest in the concept, performance evaluation, impact of instructions for use on product acceptance), and is not purely an evaluation of the safety of the product.

4.3 Discussion

4.3.1 General

The investigated wound care products have properties that differ significantly from the widely used traditional wound care products. Users of these products can not be considered to be familiar with the specific properties and risks associated with hydrocolloid dressings and wound sprays. The selection by the lay user might be prompted by catchphrases on the packaging instead of a careful consideration of the properties of the product.

In general, the assessed files were nearly complete. It is noteworthy, that the risk analysis was missing from two files. The risk analysis should be an integral part of the development of the product. However, it is also possible that the risk analysis was not available to the company that was requested to send this information.

4.3.2 Risk analysis

Although not all assessed risks are applicable to every single product, a considerable number of applicable risks are not addressed in the risk analyses. A fair number of these risks are related to use errors. These risks have not been taken into consideration for the design of the product and are not communicated to the user.

There is no risk analysis that addresses all the applicable risks. Only three risks of the 36 identified risks are covered in all files for which they were applicable.

It is noteworthy that the warning that a damaged product shall not be used was only mentioned in one of the eight instructions for use, although it was considered to be one of the most obvious risks.

Some risk analyses were not set up according to an applicable standard and/or were not well structured (e.g. mentioning risks, estimating the probability and the measures taken to reduce the risk). This could mean that there is insufficient knowledge about the possible risks and the measures to be taken, which can lead to the situation that the user is not informed about residual risks. Moreover, one file contained a risk

analysis based on a risk analysis standard (NEN-EN 1441) that was withdrawn in 2001, which could indicate that the risk analysis is not updated based on experiences reported with the products.

4.3.3 User information

For the sprays, in addition to the information on the spray cans, user information was also given on a box or a display carton, although it is likely that they will be discarded after the first use of the product. The additional information on the box or carton is then no longer available and leaves the user only with the information on the spray can. For one of the sprays, the information about the application of the spray was not on the can and will thus be lost by discarding the outer packaging. This information is considered crucial for the use of the product.

For many products, the information was given in small print, which can make it hard to read, especially for the elderly. The font size is sometimes smaller than 6 pt Times New Roman, which is considerably smaller than the 9 pt Times New Roman that was chosen as a minimum font size in this survey. This can be caused by the fact that the manufacturers try to display a lot of information in a limited space. In particular on the spray cans, the space available for user information is limited, especially if there are symbols for inflammable products and other safety warning for pressurized cans. Moreover, the information is sometimes also given in more than one language. Additionally, the information was not always clearly arranged (mainly due to alternating languages).

Concerning the content of the user information, a considerable number of items was missing. General warnings and precautions, for example not using the product when the packaging is damaged, what to do if the wound does not start to heal, are often missing. It is not realistic to think that all users are aware of the general aspects of these products.

For hydrocolloids, the specific risks for this product group were missing in a fair number of cases. Storage conditions are not included in several instructions of hydrocolloids. For one hydrocolloid dressing, this is stated on a leaflet inside the carton. This means that the user will not be aware of the right storage conditions before the first use of the product. Especially a store keeper, who will not open a product on sale, will be unaware of the appropriate storage conditions.

For wound sprays, most risks were mentioned in the user information. Probably these warnings are deemed necessary, because this product group differs considerably from the normal wound dressing and additional information is considered crucial for a safe application of the product.

The table in Appendix V indicates that for the sprays (files 10, 15 and 16), the number of items not addressed in the user information is seven or eight. For the hydrocolloid dressing the number of items missing ranges from 8 to 15, which indicates there is a marked difference in quality between the user information of the different hydrocolloid dressings.

Although not all information we considered necessary was given, the user information for these products is more elaborate than for normal plasters, and it is doubtful if the information is read by all users before they apply the products, especially because most of the products assessed will be used in stressful situations. In the separate report of Vilans, the results of application of these products in practical situations will be described.

4.3.4 Coherence

Approximately for half the products, all risks and warnings that should appear in the user information according to the risk analyses were actually present in the user information. For the other products, a few or a considerable number of risks and warnings were not mentioned in the user information. This indicates that the users will not be aware of all residual risks. For all products, additional risks and warnings were found in the user information that were not addressed in the risk analysis as residual risks to be mentioned in the user information. Striking was one product, where the two residual risks from the risk analysis were mentioned in the user information, whereas there were eight additional warnings/risks in the user information, which were not mentioned in the risk analysis. The absence of warnings from the user information in the risk analysis can be an indication of inadequate interaction between the different departments in a company working on different aspects of a product. It can also be an indication of inadequacies in the cycle of continuous product improvement. If problems occur during use and these are

subsequently mentioned only in the instructions for use, without being included in the risk analysis, the PMS and the risk management procedures are inadequate. Apparently, there is insufficient communication between the respective responsible persons for risk analysis and instructions for use. These findings are in line with the results of former studies (Roszek 2005, Roszek 2006).

4.3.5 PMS

Except for one manufacturer, PMS procedures were received for all products. Approximately half of them lacked a description of active forms of surveillance. This finding is in line with the results of former studies (Roszek 2005, Roszek 2006).

4.3.6 Test reports lay users

Only one manufacturer sent results of a study done with lay users timely, although no specific legal requirement (MDD) exists with regard to performing studies with lay users. However, this is remarkable, because these products are relatively new to the consumer market, it is unknown if the design and the information supplied are sufficient to allow safe use by first time lay users.

4.4 **Conclusions**

- In general, the assessed files were nearly complete;
- A risk analysis has not been received for two out of eight files;
- Several risk analyses were not set up according to the current risk management standard;
- Many use errors are neither addressed in the risk analyses nor in the user information. Therefore, the user information provided may be inadequate for lay users without medical knowledge;
- The coherence between the risk analyses and the user information is moderate;
- The readability of the user information is compromised by small character size. In addition, readability was found to be limited by alternating languages on the packaging;
- For wound sprays, there is a realistic possibility that crucial information is lost when the outer packaging is discarded, which can lead to use errors;
- Half of the PMS procedures only described passive forms of PMS;
- Studies with lay users were supplied for only one product before the deadline of the investigation.

5 Overall conclusions and discussion

5.1 Conclusions

Concerning the objectives of this study (in bold) the following conclusions can be drawn for the two types of devices studied:

To evaluate the completeness and quality of the supplied documentation:

- The submitted documentation was in many cases incomplete for the IR thermometers, whereas for wound dressings, most parts of documentation requested were submitted. The most striking points were the absence of risk analyses and PMS procedures.
- The quality of the submitted documentation can and should be improved in many cases. The most striking points were insufficiently addressing relevant issues in the risk analyses and user information, and lack of active forms of surveillance in PMS procedures. The items addressed in the user information and the risk analyses show in many cases moderate coherence. Moreover, the risk analyses were not all set up according to the current risk management standard.

To evaluate whether the manufacturers have considered untrained use of OTC medical devices:

- Little attention was paid to lay users in the risk analyses. Possible use errors were hardly considered and only one study with lay users was submitted.

To evaluate the suitability of the user information supplied with OTC medical devices for lay users:

- The user information of all evaluated products had shortcomings. Nevertheless, the user manuals address more residual risks than the risk analyses. The comprehensibility of the manuals was often compromised by poor readability and/or difficult phrasing. For lay users, the meaning of many EN 980 symbols cannot be supposed to be clear.

5.2 Discussion

The methods used to assess the submitted documentation were satisfactory to answer the objectives of this study. A limitation of the study was that only two product groups were selected. Although these two groups varied widely in many aspects, the results of this study do not allow comprehensive conclusions about all self-care products. To confirm these findings for other products, it is recommended to perform a similar study for other groups of OTC devices.

The findings of this study, concerning completeness of documentation and insufficiencies in risk analyses, user manuals and PMS procedures, are comparable with the results of previous investigations (Roszek, 2005, Roszek 2006). Risk analyses and PMS procedures are crucial in the continuous cycle of product improvement, which is an important principle in the MDD. Appropriate information is of utmost importance because lay users must be assumed to have no relevant knowledge and experience, especially since these products are relatively new to the consumer market.

Good coherence between the risk analysis and the user information is a sign of a well structured and properly functioning quality system. Not addressing residual risks in the user information means that the user is not aware of all risks related to the application of that product. Apparently, there is no adequate cooperation or exchange of information between the departments or individuals responsible for the risk analysis and for the user information respectively. Moreover, if the user information contains risks which are not addressed in the risk analysis, this raises questions about the procedures related to writing user information, and about the way a company deals with information about risks related to a product (e.g. post-market surveillance data, information from different departments in the company, and information published about similar products).

Although “clinical” or usability studies carried out with lay users are not explicitly legally required for OTC devices, they can provide useful information on the actual use of the products. Thorough risk management procedures would probably also indicate the desirability or even need for such studies. For a number of decades, self-care medical devices were simple products like digital thermometers, adhesive plasters or bandages. In the last years several types of devices have appeared on the consumer market which diffused from clinical settings and are rather complex. Considering the growing application of such

medical devices in self-care situations, the need for adequate evidence to confirm the safety of these products in the hands of lay users becomes more evident.

The current version of the MDD explicitly mentions that "... evaluation ... must be based on clinical data in particular in the case of implantable devices and devices in Class III" (MDD, Annex X). This phrase has led to confusion in the interpretation of the MDD. In the draft European Commission proposal of the MDD revision clinical evidence must be based on clinical data for all classes of medical devices, i.e. Class I, IIa, IIb, and III (Commission of the European Communities, 2005). Moreover, in the revision of the MDD, the consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users) will be explicitly required. This implies that, for certain OTC medical devices (e.g. new and complex devices), clinical data should be generated from "clinical use" of the device, i.e. evidence must be based on data obtained from practical testing by lay users.

6 References

General

Commission of the European Communities, Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on [...] amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives, Brussels, 2005

FDA (2001). Guidance on medical device patient labelling; Final guidance for industry and FDA reviewers. <http://www.fda.gov/cdrh/ohip/guidance/1128.html> (accessed 16-01-2006).

IVDD, The European Parliament and the Council of the European Union (2003). Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. http://www.europa.eu.int/eur-lex/en/consleg/pdf/1998/en_1998L0079_do_001.pdf

MDD, The Council of the European Communities (2003). Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. http://www.europa.eu.int/eur-lex/en/consleg/pdf/1993/en_1993L0042_do_001.pdf

MEDDEV 2.4/1 Rev. 8 of the European Commission DG Enterprise, Directorate G, Unit 4, Pressure Equipment, Medical Devices, Metrology (2001). Medical devices: Guidance document. Part 2: Guidelines for the classification of medical Devices.

NEN-EN 980: Graphical symbols for use in the labelling of medical devices, 2003, Brussels: CEN

NEN-EN 1441: Medical devices - Risk analysis, 1997, Brussels: CEN.

NEN-EN-ISO 14971: Medical devices - Application of risk management to medical devices, 2000, Brussels: CEN

Roszek, B, Drongelen, AW van, Geertsma, RE, Tienhoven, EAE van, Assessment of technical documentation of Annex II medical devices, RIVM-report 265011003, 2005, RIVM, Bilthoven

Roszek, B, Bruijn, ACP de, Drongelen, AW van, Geertsma, RE, Assessment of technical documentation of medical devices for clinical investigation, RIVM-report 360050001, 2006, RIVM, Bilthoven

Thermometers

ASTM 1965-98: Standard Specification for infrared thermometers for intermittent determination of patient temperature. August 1998.

Craig, J. V., Lancaster, G. A., Taylor, S., Williamson, P. R., & Smyth, R. L. (2002). Infrared ear thermometry compared with rectal thermometry in children: a systematic review. *Lancet* **360**, 603-609.

Dodd, S. R., Lancaster, G. A., Craig, J. V., Smyth, R. L., & Williamson, P. R. (2006). In a systematic review, infrared ear thermometry for fever diagnosis in children finds poor sensitivity. *J.Clin.Epidemiol.* **59**, 354-357.

ECRI (1998). Ear thermometer accuracy — talk to the specialist. *Health Devices* **27**, 368-369.

Lanham, D. M., Walker, B., Klocke, E., & Jennings, M. (1999). Accuracy of tympanic temperature readings in children under 6 years of age. *Pediatr.Nurs* **25**, 39-42.

MHRA, Medical and Healthcare products regulatory agency Thermometer review: UK market survey 2005. MHRA 04144, 1-84. 2005. Londen.

MHRA, Medical and Healthcare products regulatory agency. Medical Device Alert: Ear thermometer — Home Use; MDA/2003/10. 3 A.D. London, MHRA.

NEN-EN 12470-5: Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device). 2003.

NEN-EN-IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, 2006

NEN-EN-IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard - Electromagnetic compatibility - Requirements and tests, 2001

Ng, D. K., Chan, C. H., Chan, E. Y., Kwok, K. L., Chow, P. Y., Lau, W. F., & Ho, J. C. (2005). A brief report on the normal range of forehead temperature as determined by noncontact, handheld, infrared thermometer. *Am.J.Infect.Control* **33**, 227-229.

Nimah, M. M., Bshesh, K., Callahan, J. D., & Jacobs, B. R. (2006). Infrared tympanic thermometry in comparison with other temperature measurement techniques in febrile children. *Pediatr.Crit Care Med.* **7**, 48-55.

Pusnik, I., van der Ham, E., & Drnovsek, J. (2004). IR ear thermometers: what do they measure and how do they comply with the EU technical regulation? *Physiol Meas.* **25**, 699-708.

Pusnik, I. & Drnovsek, J. (2005). Infrared ear thermometers—parameters influencing their reading and accuracy. *Physiol Meas.* **26**, 1075-1084.

Riddell, A. & Epprich, W. (2001). Shoul tympanic temperature measurement be trusted? *Arch.Dis.Child.* **85**, 433-434.

Sievert, U., Pau, H. W., & Weidemann, T. (1999). Das “Ohr-Fieberthermometer”—Untersuchungen zur Ohrthermographie. [The “ear fever thermometer”—studies of ear thermography]. *Laryngorhinootologie* **78**, 397-400.

Simon, M. W. (1996). Children with unilateral acute otitis media may have a temperature differential when both ears are measured by an infrared ear thermometer. *Pediatr.Emerg.Care* **12**, 324.

Suleman, M. I., Doufas, A. G., Akca, O., Ducharme, M., & Sessler, D. I. (2002). Insufficiency in a new temporal-artery thermometer for adult and pediatric patients. *Anesth.Analg.* **95**, 67-71,table.

Wound care products

Casper, A. OTC Product: Band-aid liquid bandage (2006). *Journal of the American Pharmacist Association*, **46** (6), 768.

Claus et al. (1998). Comparison of the effects on selected dressings on the healing of standardized abrasions. *Journal of Athletic training*, **33**(2): 145-149

Finnie A (2002). Hydrocolloids in wound management: pros and cons. *British Journal of Community Nursing*, **7**(7): 338, 340-342.

Hageman, A. & Klaucke, C. Decubitus: wondzorg volgens het TIME-concept. Houd de wond gezond. *Nursing*, September 2005, p. 34-38

Heenan, A. (1998). Hydrocolloid Dressings, Frequently asked questions. www.worldwidewounds.com (consulted 2-10-2006)

Hess, C.T. (2000) When to use hydrocolloid dressings. *Advances in skin & wound care*, **13**(2), p 63-64.

Thomas, S. & Loveless, P. (1997), A comparative study of properties of twelve hydrocolloid dressings. www.worldwidewounds.com. (consulted 23-10-2006)

Appendix I – Selected products and respondents⁸

Product category	Respondent
<u>IR-thermometer:</u>	
Ear	
Braun IRT 4020	Procter & Gamble Nederland B.V.
Cresta Ear thermometer TH 838	Sabre Nederland BV
Happylife	Medisana Benelux N.V.
Kruidvat Ear thermometer Infrared	A.S. Watson
Principal Ear thermometer ET-100	Blokker B.V.
Forehead	
Inventum MT 50	Martex Holland B.V.
Microlife FR 1DM1	Retomed
Combined	
Medisana Infrared thermometer FTD	Medisana Benelux N.V.
<u>Wound Care products:</u>	
Hydrocolloids	
Compeed 3 in 1 Dual Zone Technology	Johnson & Johnson Consumer B.V.
Hansaplast Active Gel Strip Medium ^a	Beiersdorf N.V.
Kruidvat Active Gel Strips	A.S. Watson
Nexcare Gels Strip Finger	3M Nederland B.V.
Scholl Transparant Hydra-Gel Blister Plaster	SSL Healthcare Nederland N.V.
Sprays	
Hansaplast Spray Bandage	Beiersdorf N.V.
HetltiQ Stops bleeding Spray	Koninklijke Utermöhlen N.V.
Kruidvat Spray Bandage	Koninklijke Sanders B.V.

⁸ The results in the following annexes are presented using randomly assigned file numbers, ensuring that results can not be traced back to a specific product.

Appendix II – Completeness of files per respondent

IR thermometers: received documents per file

File number:	Risk analysis	Instructions for use	Label on device	Packaging	PMS procedure	Vigilance procedure**	Test report (lay user)	Test report (professional user)**
1.	+	+	+	+	-	-	-	-
2.	+	+	+	+	-	-	-	+
3.	+	+	+	+	-	-	-	+
4.	+	+	+	+	+	+	-	-
5.	-	+	+	+	-	-	-	-
6.	-	+	+	+	-	-	-	-
7.	-	+	+	+	-	-	-	-
8.	-	+	+	+	-	-	-	-

* Not requested by the IGZ

+ = present

- = absent

NA = not applicable

Continued: Appendix II Completeness of files per respondent

Wound care products: received documents per file

Files number:	Risk analysis	Instructions for use	Label on device	Packaging	PMS procedure	Vigilance procedure*	Test report (lay user)	Test report (professional user)*
9	+	+	NA	+	+	+	+	-
10.	+	+	+	+	+	-	-	-
11.	-	+	NA	+	+	+	-	-
12.	+	+	NA	+	-	+	-	-
13.	+	+	NA	+	+	-	-	-
14.	+	+	NA	+	+	+	-	-
15.	+	+	+	-	+	-	-	-
16.	-	+	+	+	+	+	-	-

* Not requested by the IGZ

+ = present

- = absent

NA = not applicable

Appendix III – File assessment IR-thermometers**1. Assessment risk analyses**

File number	1	2	3	4	5	6	7	8
Items named in the <u>risk analyses</u> of manufacturers:								
Design and specifications								
filtering effects of optical components, including probe cover	+	-	-	-				
Effects of differences in emissivity of the measured surface	-	-	-	-				
influence of local environmental conditions (ambient temperature, humidity)	-	-	-	+				
influence of differences in age (neonates, adults, elder people)	-	-	-	-				
measured temperature outside range specified by manufacturer	-	-	-	-				
Effects of the temperature of the thermometer/drift	-	-	-	-				
inaccurate readings/low accuracy	+	+	+	+				
readings critical for subgroups of patients (repeating of measurement)	-	-	-	-				
wrong temperature calibration by manufacturer	-	+	+	+				
influence of no or low power supply	+	-	-	-				
manufacturing standards	+	+	-	+				
Use errors (thermometers general)								
use by unskilled users	+	-	-	+				
insufficient user instruction	+	-	-	+				
incorrect reading or interpretation of displayed temperature (e.g. °F vs. °C)	+	-	-	+				
incorrect positioning of the thermometer	+	-	-	+				
influence of exercise, sleep, bathing, eating, talking before/during measuring	-	-	-	-				
User maintains an insufficient time interval between two measurements	-	-	-	-				
cross infection (insufficient cleaning or decontamination)	+	+	+	+				
measurement just after cleansing of the thermometer	-	-	-	-				
operating outside prescribed environmental temperature	+	-	-	-				
Use errors (applicable to ear thermometers)								
manipulation of the probe	-	NA	-	NA				
not using probe covers (if applicable)	+	NA	NA	NA				
improper use of probe covers (wrong type/not clean/wrong installation)	+	NA	NA	NA				

influence of ear anatomy, e.g. long, narrow, curvy ear canal	-	NA	-	NA				
influence of obstructions in the ear canal, e.g. ear wax	-	NA	-	NA				
influence of ear laying on pillow or mattress just before measuring	-	NA	-	NA				
differences between left and right ear in repeated measurements	-	NA	-	NA				
Use errors (applicable to forehead thermometers)								
incorrect distance to the skin	NA	-	NA	-				
forehead covered just before measuring: e.g. scarf, hat, cap	NA	-	NA	-				
forehead covered with e.g. make-up	NA	-	NA	-				
hair on forehead	NA	-	NA	-				
forehead perspiring	NA	-	NA	-				
cold compresses on the forehead just before measuring	NA	-	NA	-				
coming from outside just before measurement	NA	-	NA	-				
lamplight or sunlight on the forehead	NA	-	NA	-				
influence of moving air from air conditioning or draught	NA	-	NA	-				
Technical failures								
failure of the IR sensor/probe: e.g. breaking	+	+	+	+				
defects of software/firmware/settings	+	-	-	+				
failure of or incorrect information on the display	+	-	-	+				
electromagnetic interference	+	-	-	+				
harmful effects on accuracy of dropping	-	+	+	+				
harmful effects on accuracy of extreme circumstances	+	-	-	-				
effects of penetration of water or other fluids	-	-	-	-				
Storage, maintenance and calibration								
storage conditions outside range specified by manufacturer	+	-	-	+				
remove battery before storage to prevent damage by leakage	-	+	+	-				
low battery	+	-	-	-				
incorrect battery replacement	-	-	-	-				
incorrect cleaning: e.g. immersion in fluids, use of aggressive chemicals	+	-	-	-				

+ = manufacturer considers item in risk analysis

- = manufacturer does not consider item in risk analysis

NA = item not applicable to assessed product

= document not received, no assessment possible

2. Assessment user information

File number	1	2	3	4	5	6	7	8
Items named in the <u>instructions for use</u>:								
Design and specifications								
Intended body site, e.g. ear	+	+	+	+	+	+	+	+
displayed temperature (body temperature, core temperature)	-	+	+	+	+	+	+	-
subject categories: new-born/children/adults + warning	-	+	+	+	+	-	-	-
local environmental conditions (e.g. ambient temperature, humidity)	+	+	+	+	+	+	+	+
only to be used for measuring body temperature	-	+	NA	+	-	-	+	NA
measuring range	-	+	+	+	+	+	+	+
description of the self-testing sequence and other warnings	+	+	+	+	+	+	+	+
correct sensor position	-	+	+	+	+	-	+	+
upper limit of normal temperature or signal in case of fever	-	+	+	+	-	-	-	-
minimum time between two measurements	-	-	+	+	-	+	+	+
precautions with respect to the safety of operators and patients	-	+	+	+	+	+	+	+
list of offsets and associated algorithm(s) used to calculate estimated modes	-	-	-	-	-	-	-	-
CE	+	-	-	+	+	+	+	+
code notified body	+	-	-	+	+	+	+	+
reference to European standard EN 12470-5 + complete title (both required)	+	-	-	-	+	+	-	-
if no reference to EN 12470-5: reference alternative standard(s)	NA	+	+	+	NA	NA	-	-
name manufacturer or European authorized representative	+	+	+	+	+	-	+	+
full address manufacturer or European authorized representative	+	+	-	+	+	-	+	+
Use errors (ear thermometer)								
check if the ear canal is dry	-	NA	-	NA	-	-	-	-
check if the ear canal is clean	+	NA	+	NA	+	+	+	+
check if the thermometer lens is clean	-	NA	+	NA	+	+	-	+
do not exercise before/during measurement	-	NA	-	NA	-	-	-	+
do not talk during measurement	-	NA	-	NA	-	-	-	-
do not measure the ear that has just been lying on a pillow	-	NA	+	NA	+	-	-	+

or mattress								
do not take a reading within 30 minutes of a bath, shower or swimming	-	NA	-	NA	+	-	-	+
compare measurements of the same ear	-	NA	+	NA	+	-	+	+
do not measure just after medication (ear drops)	-	NA	-	NA	+	-	-	-
how to apply probe cover	+	NA	NA	NA	+	-	-	NA
specification whether probe cover is intended for single or multiple use, if app.	-	NA	NA	NA	+	+	+	NA
if multiple use is intended, cleaning instructions probe covers	+	NA	NA	NA	NA	NA	NA	NA
if multiple use is intended, criteria when probe cover should be discarded	-	NA	NA	NA	NA	NA	NA	NA
Use errors (Forehead thermometer)								
avoid moving air: e.g. air conditioning, draught	NA	-	NA	-	NA	NA	NA	-
the forehead should not be perspiring	NA	+	NA	+	NA	NA	NA	-
the forehead should not be covered with e.g. makeup	NA	+	NA	-	NA	NA	NA	-
avoid measuring skin that is close to a lamp or exposed to sunlight	NA	-	NA	-	NA	NA	NA	-
do not take readings short after exercise	NA	+	NA	-	NA	NA	NA	+
do not take readings short after bathing, showering	NA	-	NA	-	NA	NA	NA	+
do not take readings short after drying hair	NA	-	NA	-	NA	NA	NA	-
do not take readings short after wearing e.g. a scarf, hat, cap etc.	NA	-	NA	-	NA	NA	NA	-
do not take readings short after having a cold compress on the head etc.	NA	-	NA	-	NA	NA	NA	-
do not take readings on forehead baby short after feeding a baby (may cause lower values)	NA	+	NA	-	NA	NA	NA	-
move hair away from forehead skin	NA	+	NA	-	NA	NA	NA	-
Technical failures								
failure of the IR sensor/probe: e.g. breaking	-	+	+	+	-	-	+	-
defects of software/firmware/settings	+	+	+	-	+	-	+	-
failure of or incorrect information on the display	-	+	-	-	-	+	+	-
prevent mechanical shock, e.g. dropping	-	+	+	+	-	-	-	+
prevent extreme circumstances	+	+	+	+	+	+	+	+
prevent water or other fluids	+	+	+	+	+	-	+	+
trouble shooting guide	+	+	+	+	+	-	+	-

address for service, calibration and repair	+	-	+	+	+	-	+	+
Storage, maintenance, calibration								
storage conditions (humidity, temperature)	+	+	+	+	+	+	+	+
low battery	+	+	+	+	+	+	+	+
battery replacement	-	+	+	+	+	+	+	+
instructions + precautions for proper cleaning/disinfection/sterilization	+	+	+	+	+	+	+	+
frequency of recalibration	NA	+	-	NA	NA	+	-	NA
information on how to obtain maintenance or calibration service	+	+	+	+	+	-	+	+
disposal of the thermometer	-	+	+	+	+	+	+	+

+ = present in manual

- = absent in manual

NA = item not applicable to assessed product

. = document not received, no assessment possible

Readability of the instructions for use	1	2	3	4	5	6	7	8
information in Dutch	+	+	+	+	+	+	+	+
correct usage (language)	-	+	+	+	+	+	-	-
readable (character size)	+	-	-	-	+	-	-	-
clear arrangement	-	+	+	+	+	+	+	+
explanation terms (e.g. by means of schematic drawing)	+	+	+	-	+	+	+	+
explanation symbols (on display or packaging)	+	+	+	+	+	-	+	+

+ = yes

- = no

File number	1	2	3	4	5	6	7	8
Items named on the <u>label</u>:								
brand, type	+	+	-	+	+	+	+	+
body site (ear, forehead)	-	-	-	-	-	-	+	-
whether probe covers have to be used	-	NA	-	NA	-	-	+	-
the symbol "°C" adjacent to the numerical value, if not on display	NA	NA	NA	NA	NA	NA	NA	NA
displayed temperature (body temperature, core temperature)	-	-	-	-	-	-	-	-
year and month of manufacture, and of first calibration if different	-	-	-	-	-	+	-	-
warning: read instructions before use or symbol	+	+	-	+	+	-	+	+
name manufacturer/European representative	-	+	+	+	+	-	+	+
full address manufacturer/European representative	-	-	-	-	-	-	-	-
CE	+	+	-	+	+	+	+	+
Notified Body	+	+	-	+	+	+	+	+
information on label in Dutch	NA	NA	NA	NA	NA	NA	-	NA

+ = present on label

- = absent on label

NA = item not applicable to assessed product

File number	1	2	3	4	5	6	7	8
Items named on the <u>packaging</u>:								
brand, type	+	+	+	+	+	-	+	+
body site (ear, forehead)	+	+	+	+	+	+	+	+
whether probe covers have to be used	-	NA	+	NA	+	-	+	+
the symbol "°C" adjacent to the numerical value. Not applicable (NA) if symbol on the display	NA	NA	NA	NA	NA	NA	NA	NA
displayed temperature (body temperature, core temperature)	-	-	+	-	+	-	+	+
year and month of manufacture, and of first calibration if different	-	-	-	-	-	-	-	-
warning: read instructions before use or symbol	-	+	+	-	+	+	-	-
name manufacturer/European representative	+	+	+	+	+	+	-	+
full address manufacturer/European representative	+	+	-	+	+	-	-	-
CE	+	+	+	+	+	+	+	+
Notified Body	+	+	+	+	+	+	+	+
information on label in Dutch	+	-	+	+	+	+	+	+

+ = present on label

- = absent on label

NA = item not applicable to assessed product

Appendix IV – File assessment wound care products

File number	9	10	11	12	13	14	15	16
Items named in the <u>risk analysis</u> of manufacturers:								
Design and Specifications (general)								
product does not meet specifications, also incorrect formula of content spray	+	-		+	-	+	+	
damage of product/risk of defects (packaging)	-	+		+	-	+	-	
skin irritation by components of product	+	+		+	-	+	+	
interaction with other devices or drugs or substances, including water on skin	+	+		-	-	+	+	
long-term use has been considered	+	NA		+	+	-	-	
product which is labelled as sterile may not be sterile	NA	NA		NA	+	NA	NA	
insufficient user instruction/unclear user instruction	+	-		+	-	-	+	
expired product	+	+		+	+	-	+	
Design and Specifications (hydrocolloids)								
microbiological contamination during production process/packaging	+	NA		+	-	-	NA	
low absorption (maceration)	-	NA		+	+	+	NA	
high absorption (may damage wound bed)	-	NA		+	+	+	NA	
product adheres too strongly (skin damage)	-	NA		+	+	+	NA	
product does not adhere (early detachment)	-	NA		+	+	+	NA	
open wrapper or seal (product dries out)	+	NA		+	+	+	NA	
Use errors (general)								
use on deeply injured skin or heavily exudating wounds	+	+		+	-	NA	+	
use on infected skin/wound/blister	-	-		-	+	+	+	
use on (severe) burns	-	NA		-	-	-	+	
use on dirty skin	+	-		+	-	+	-	
use on wet skin	+	-		+	-	+	-	
use by unskilled users	-	+		+	+	-	+	
risk of misunderstanding product or wrong product is used	+	+		-	+	+	+	
no relevant information is available to user (loss of instruction/packaging)	+	-		-	-	+	NA	
Use errors (hydrocolloids)								
use by patients with diabetes (sensory loss, ulcers, infection, delayed healing)	+	NA		-	-	+	NA	
touching of adhesive by user before application of dressing	-	NA		+	-	-	NA	

incorrect dressing size (may delay wound healing; mechanism fails)	-	NA		-	+	-	NA	
adhesive placed over wound	-	NA		-	-	+	NA	
damage to wound bed on removal	-	NA		+	+	+	NA	
dressing removed too late (may cause maceration)	-	NA		+	+	+	NA	
Use errors (sprays)								
contact with the eye	NA	+		NA	NA	NA	+	
spraying at mucosa	NA	-		NA	NA	NA	+	
internal use	NA	-		NA	NA	NA	+	
explosion of device by electrostatic interference/spraying to sources ignition	NA	+		NA	NA	NA	+	
piercing or burning can	NA	+		NA	NA	NA	-	
keeping within reach of children	NA	+		NA	NA	NA	-	
human contact with spray nozzle	NA	-		NA	NA	NA	+	
Storage, maintenance, calibration								
inadequate (may cause change in product/degradation)	+	+		-	+	-	+	

+ = item considered in risk analysis

- = item not considered in risk analysis

NA = item not applicable to assessed product

= document not received, no assessment possible

File number	9	10	11	12	13	14	15	16
Items named in the <u>user information</u>:								
Design and specifications (general)								
Brand, type	+	+	+	+	+	+	+	+
intended use: type of wound	-	+	-	+	+	+	+	+
intended use: body site	-	NA	-	-	NA	+	NA	+
expiry date (year and month)	+	+	+	+	+	+	+	+
batch code	+	+	+	+	+	+	+	+
name manufacturer or European representative	+	+	+	+	+	+	+	+
full address manufacturer or European representative	-	-	-	-	-	-	+	-
CE	+	+	+	+	+	+	+	+
Notified Body	+	+	+	+	+	-	NA	+
Design and specifications (hydrocolloids)								
single use product (e.g. symbol on packaging)	+	NA	-	-	+	+	NA	NA
product is sterile (e.g. symbol on packaging)	NA	NA	-	NA	+	NA	NA	NA
Instructions for use (general)								
instruction how to apply (e.g. spraying distance)	-	+	+	+	+	+	+	+
clean wound/skin before use	-	+	+	+	+	+	+	+
use on dry skin	+	-	+	+	+	+	+	+
when to stop using	-	-	+	+	-	+	-	-
when to remove product	-	-	+	NA	+	-	-	+
Use errors (general)								
do not use if packaging is damaged	-	-	-	+	-	-	-	-
do not use on deeply injured skin	+	NA	-	-	-	-	+	+
do not use on infected wounds/skin	+	-	+	-	-	-	+	+
do not use on severe burns	-	NA	-	-	-	-	+	+
what to do if signs of infection or irritation occur	-	-	+	+	-	-	-	-
what to do if wound/blister does not start to heal	-	-	-	+	-	-	-	-
what to do if bleeding does not stop	-	+	-	-	-	-	-	-
Use errors (hydrocolloids)								
warning: use in diabetic diseases (e.g. consult doctor)	+	NA	-	-	-	+	NA	NA
warning: do not touch adhesive	-	NA	-	+	+	-	NA	NA
warning: ensure pouch seal is intact before use	-	NA	-	+	+	-	NA	NA
Use errors (sprays)								
warning: do not pierce or burn can	NA	+	NA	NA	NA	NA	+	+

warning: do not spray in eyes	NA	+	NA	NA	NA	NA	+	+
warning: do not spray at mucosa	NA	+	NA	NA	NA	NA	+	+
warning: do not spray in direction of sources of ignition / flammable	NA	+	NA	NA	NA	NA	+	+
warning: keep out of reach children	NA	+	NA	NA	NA	NA	+	+
warning: do not inhale	NA	+	NA	NA	NA	NA	-	+
instruction how to remove product from skin	NA	NA	NA	NA	NA	NA	+	-
Storage								
special storage conditions (cool, dry, away from direct sunlight)	-	+	-	+	+	-	+	+

+ = present in manual

- = absent in manual

NA = item not applicable to assessed product

= document not received, no assessment possible

Readability	9	10	11	12	13	14	15	16
information in Dutch	+	+	+	+	+	+	+	+
correct usage (language)	+	+	+	+	+	+	+	+
readable (character size)	-	-	+	-	-	-	-	-
clear arrangement	-	+	+	+	+	-	-	-
explanation of term infection (redness, increased pain etc.)	-	-	+	-	-	-	-	-
explanation of other terms	NA	NA	-	NA	NA	NA	NA	NA
explanation of symbols	NA	-	NA	NA	NA	NA	+	+

+ = yes

- = no

NA = not applicable

Appendix V – Scores for user information per file

IR-thermometer file no.	1	2	3	4	5	6	7	8
Number of items <u>not</u> addressed in the user information (total number of items: n=58)	24	12	12	14	10	22	15	22
Wound care product file no.	9	10	11	12	13	14	15	16
Number of items <u>not</u> addressed in the user information (total number of items: n=34)	15	8	14	8	10	13	7	7