Physikalisch-Technische Bundesanstalt
National Metrology Institute

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Leaflet: Software Risk Assessment – Guidelines for Manufacturers

1 Introduction

The aim of this leaflet is to provide recommendations for manufacturers of measuring instruments who submit their instruments to the conformity assessment body of PTB for Module B type examination, according to the European Measuring Instruments Directive (MID) [1] or to the Measures and Verification Act (Mess- und Eichgesetz - MessEG) [2]. In both legal frameworks, the manufacturer is required to provide a suitable risk assessment of the instrument, regarding essential requirements, in addition to the documentation of the measuring instrument and the software (Annex I of the MID [1], or Annex 2 to the Measures and Verification Ordinance (Mess- und Eichverordnung - MessEV) [3]). This leaflet explains in detail how to apply the risk assessment procedure harmonized in WELMEC Guide 7.6 [4]. Additional details on the procedure may be found in the original publication [5].

A risk assessment is explicitly required in the MID [1] modules A, A2, B, D1, E1, F1, G, H, and H1. This regulation has been transposed into the national legislation in § 10 MessEV [3], in conjunction with §§ 7 and 8 MessEV [3].

WELMEC Guide 7.6 [4] provides an assets-based approach to risk analysis. Assets to be protected are derived from the corresponding requirements in MID [1], which are also applicable to MessEV [3], see Section 2.

For measuring instruments from all risk classes (see WELMEC 7.2 Software Guide [6]), WELMEC Guide 7.6 [4] requires that the manufacturer demonstrates (by means of an extensive table) how generic threats to assets are addressed. Further details on the generic threats and the table are given in Section 0. For measuring instruments in risk classes D to F, WELMEC Guide 7.6 [4] also asks manufacturers to identify additional instrument-specific threats to be addressed in a separate risk analysis. The procedure to be followed during identification and evaluation of these additional threats is described in Section 4.

2 Assets to be protected

Every measuring instrument that is examined during a conformity assessment based on the MID [1] or the MessEG [2] must fulfill the essential software requirements listed in column 1 of Table 1. These requirements are commonly interpreted in the form of **assets** (column 2) with their associated generic **security properties** (column 3), see [4].

Table 1: Correspondence between the software-related essential requirements, their derived assets to be protected, and their associated security properties

Software-related essential requirement in Annex I of the MID or Annex 2 of the MessEV	Assets	Security property
7.6 When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.	identification of the legally relevant software	availability, integrity
	inadmissible influence on the legally relevant software through other software	non-availability[1]
8.1 The metrological characteristics of a measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the measuring instrument.	inadmissible influence on the legally relevant software via communication interfaces	non-availability
8.3 Software that is critical for metrological characteristics shall be identified as such and shall be secured. Software identification shall be easily provided by the measuring instrument. Evidence of an intervention shall be available for a reasonable period of time.	presentation of the software identification	Availability
	evidence of an intervention	availability, integrity
8.2 A unit, decisive for the measuring technology features, must be designed, in such a way that it can be secured. The provided protective measures must allow proof of possible interventions. 8.4 Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.	measurement data	integrity, authenticity
	legally relevant software that is critical for metrological characteristics	integrity, authenticity
	metrologically important parameters	integrity, authenticity
10.1 Indication of the result shall be by means of a display or hard copy.	indication of the result	availability, integrity
10.2 The indication of any result shall be clear and unambiguous and accompanied by such marks and inscriptions necessary to inform the user of the significance of the result. Easy reading of the presented result shall be permitted under normal conditions of use. Additional indications may be shown, provided they cannot be confused with the metrologically controlled indications.	clear and unambiguous indication of the result, marks and inscriptions accompanying a measurement result	availability, integrity
11.1 A measuring instrument other than a utility measuring instrument shall record by a durable means the measurement result accompanied by information to identify the particular transaction, when: (a) the measurement is non-repeatable; and (b) the measuring instrument is normally intended for use in the absence of one of the trading parties. 11.2 Additionally, a durable proof of the measurement result and the information to identify the transaction shall be available on request at the time the measurement is concluded.	record of a measurement result and necessary additional information	availability

[1] The term “non-availability” should be interpreted as follows: “There shall be no inadmissible influence on the legally relevant software.”

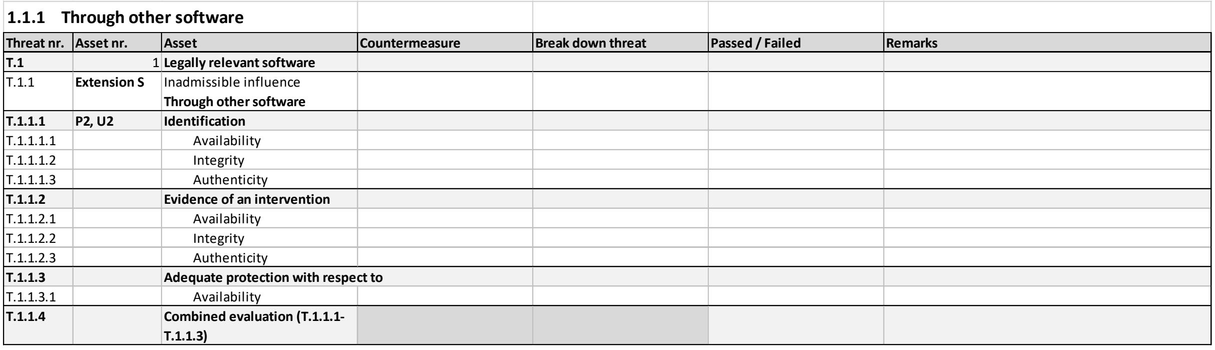
3 Generic threats to assets with high-level attack vectors

For each asset, WELMEC Guide 7.6 [4] provides a list of generic threats with associated high-level attack vectors which need to be countered by the measuring instrument to demonstrate compliance with the essential requirements from MID [1]. The Guide summarizes these as follows:

> *"An attacker attacks the software, parameters, measurement result,*
> *stored result or indication through*
>
> - *Other software*
> - *User Interface*
> - *Communication interface*
>   - *Direct influence by connecting a device to the measurement instrument*
>   - *Through transmission (including software downloads)*
> - *Connecting a device to the instrument*
> - *Replacing hardware.*
>   - *Replacing complete parts*
>   - *Replacing components*
> - *Replacing software (for Type U instruments*)"*

To help manufacturers address each high-level attack vector for each generic threat, an extensive table in the form an annex to WELMEC Guide 7.6 [4] has been published: *https://www.welmec.org/welmec/documents/guides/7.6/2021/WELMEC_Guide_7.6_v2021_Annex_1_Riskanalysis.xlsx*

It may be assumed that a completely filled in table serves as a sufficient risk analysis for measuring devices up to risk class C. An excerpt from the table is shown in *Figure 1* below, for an example see Annex A.



1.1.1 Through other software

Threat nr.	Asset nr.	Asset	Countermeasure	Break down threat	Passed / Failed	Remarks
T.1	1	**Legally relevant software**				
T.1.1	**Extension S**	Inadmissible influence **Through other software**				
T.1.1.1	**P2, U2**	**Identification**				
T.1.1.1.1		Availability				
T.1.1.1.2		Integrity				
T.1.1.1.3		Authenticity				
T.1.1.2		**Evidence of an intervention**				
T.1.1.2.1		Availability				
T.1.1.2.2		Integrity				
T.1.1.2.3		Authenticity				
T.1.1.3		**Adequate protection with respect to**				
T.1.1.3.1		Availability				
T.1.1.4		**Combined evaluation (T.1.1.1-T.1.1.3)**				

Figure 1: List of generic threats to software with high-level attack vectors from Annex I in [4].

Column 1 in the table simply lists a threat ID. References to the requirements from WELMEC 7.2 Software Guide [6] are provided in column 2. Asset name and associated security property are given in column 3. Manufacturers are required to fill in the complete table by providing countermeasures to each listed threat (4th column of the table) and giving details on how the threat might be implemented in column 5. Column 6 is intended to be used by the conformity assessment body, column 7 may be used to provide additional remarks.

4 Identification of additional threats and of possible attack scenarios

4.1 Basic concept of the risk analysis

The norm ISO/IEC 27005 [7] defines risk as a combination of the consequences (impact), which follows from an unwanted event (threat), and the probability of occurrence of the threat. Thus, the risk associated with a threat can be modeled by the following equation:

$$\text{risk} = \text{impact} \times \text{probability of occurrence}$$

In the context of legal metrology, the term impact refers to a breach of the essential requirements. These essential requirements can be understood as the characteristics of the protection objectives of the MID [1] (taking in consideration [8]).

Concerning **the impact**, only two categories are defined here:

a. The impact resulting from a threat is considered to be low (factor $\frac{1}{3}$), when a threat only affects an essential requirement only once and only for a short period of time.

b. In all other cases an impact factor of 1 is assumed.

4.2 Identification of threats and attack vectors

The invalidation of any one of the assets to be protected can be considered a relevant threat in the context of this leaflet. Based on the instrument and the submitted documents for conformity assessment, the manufacturer shall explain which threats (invalidation of the security properties of one or more assets) can be realized by specific technical steps. The manufacturer is kindly asked to describe, for each security property of an asset, which steps would be theoretically necessary to invalidate the respective security property. Where applicable, it shall be demonstrated that the invalidation of a security property is intrinsically impossible. Lists of current attack scenarios for measuring instruments that are, for example, connected to the Internet may, for instance, be found at *https://www.enisa.europa.eu/activities/risk-management/evolving-threat-environment* or at *https://cve.mitre.org/*.

4.3 Calculation of the probability of occurrence

For each identified attack scenario, the manufacturer shall evaluate which prerequisites a possible attacker should have to successfully implement an attack. It is recommended to base the evaluation on the following five criteria:

1. Elapsed Time (0-19 points)
2. Expertise (0-8 points)
3. Knowledge of the measuring system (0-11 points)
4. Window of opportunity (0-10 points)
5. Equipment (0-9 points)

For each criterion a point score shall be assigned, based on the tables given in Annex B. Depending on the sum of all points, each attack scenario is then given a probability score, as described in the following table. Details concerning the assessment scheme may also be found in the standard ISO/IEC 18045 "Information technology – Security techniques - Methodology for IT security evaluation" [9], part 2, B.4.2.2 ff. An example may be found in Annex C.

Table 2: Mapping of point scores according to [9]

Sum of point scores	Resistance to attacks	Probability score
0-9	No rating	5
10-13	Basic	4
14-19	Enhanced basic	3
20-24	Moderate	2
>24	High	1

4.4 Calculation of the impact

If a threat affects an unlimited number of future or past measurements, then the impact shall be set to 1. If only individual measurements are affected by the threat, then an impact of $\frac{1}{3}$ is assumed.

4.5 Calculation of the risk

Finally, the determined probability of occurrence is transformed into a risk, while taking into account the estimated impact. To this end, impact and probability of occurrence are multiplied. Afterwards, if necessary, the result is rounded up to the next integer number. A detailed description of the entire procedure, with additional examples, may be found in [5].

4.6 Consequences

As a general rule, all threats with a risk of 4 or 5 must be mitigated by technical or organizational measures until, after a new assessment, a risk in the range between 1 and 3 is reached.

5 References

[1] “Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast),” *Official Journal of the European Union, L 96/149,* 29 March 2014.

[2] „Gesetz über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt, ihre Verwendung und Eichung sowie über Fertigpackungen (Mess- und Eichgesetz – MessEG),“ *Bundesgesetzblatt, Volume 2013 Part 1 No. 43,* July 2013, last modified on 11. April 2016.

[3] „Verordnung über das Inverkehrbringen und die Bereitstellung von Messgeräten auf dem Markt sowie über ihre Verwendung und Eichung (Mess- und Eichverordnung – MessEV),“ *Bundesgesetzblatt, Volume 2014 Part 1 No. 58,* December 2014, last modified on 11. August 2017.

[4] WELMEC, *WELMEC Guide 7.6: Software Risk Assessment for Measuring Instruments,* 2021.

[5] M. Esche und F. Thiel, „Software Risk Assessment for Measuring Instruments in Legal Metrology,“ in *Proceedings of the Federated Conference on Computer Science and Information Systems, Volume 5*, Lodz, Poland, September 2015, DOI: http://dx.doi.org/10.15439/978-83-60810-66-8, ISSN 2300-5963, (2015).

[6] WELMEC, *WELMEC 7.2, Software Guide (Measuring Instruments Directive 2014/32/EU),* 2020.

[7] „ISO/IEC 27005:2011(e) Information technology - Security techniques - Information security risk management,“ International Organization for Standardization, Geneva, CH, Standard, June 2011.

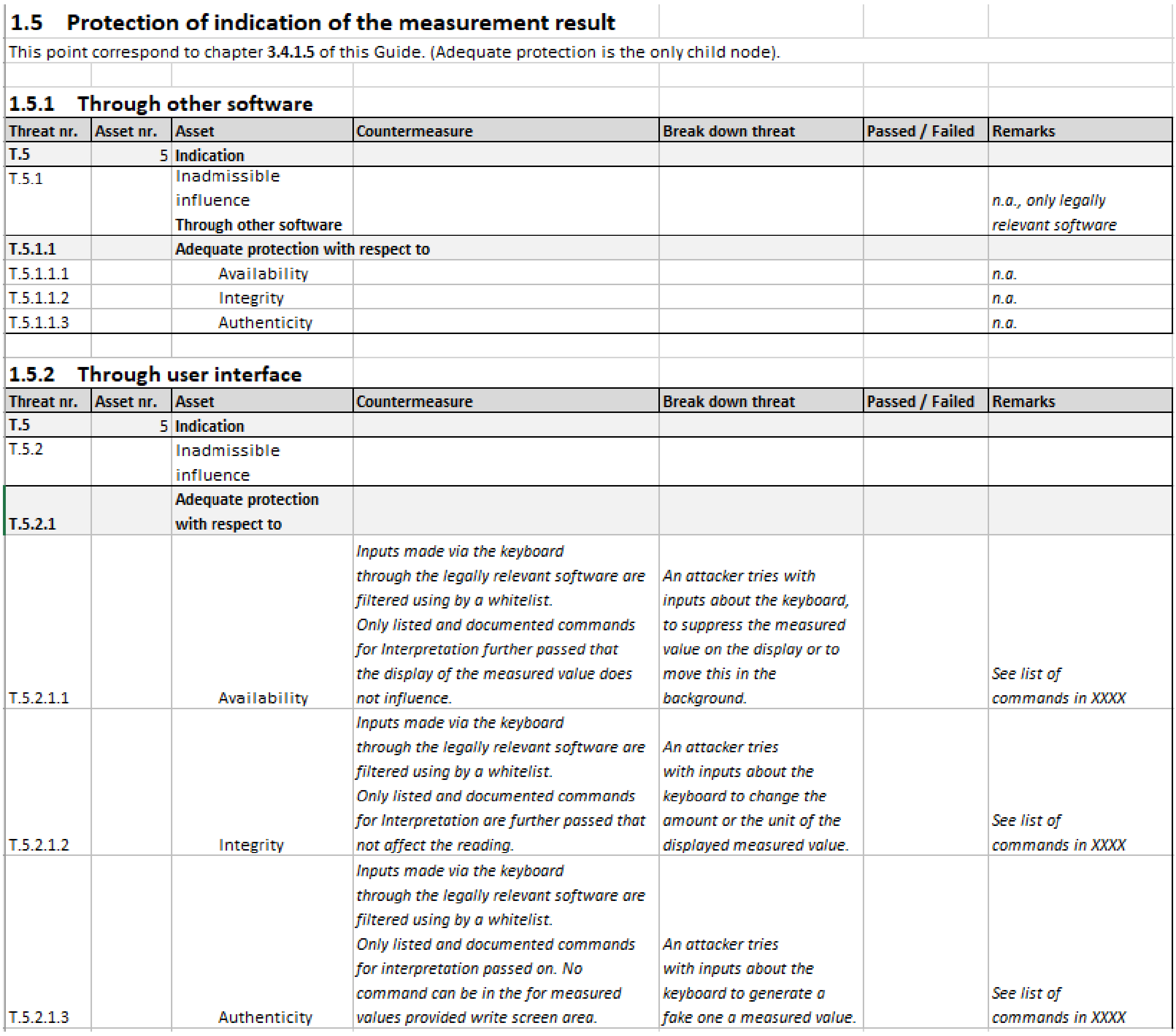
[8] „The 'Blue Guide' on the implementation of EU product rules,“ Council of the European Union, Version 1.1, July 2015.

[9] „ISO/IEC 18045:2008 Information technology – Security techniques – Methodology for IT security evaluation,“ International Organization for Standardization, Geneva, CH, Standard, August 2008.

Annex A: Exemplary risk analysis of generic threats to assets with high-level attack vectors

The following example considers a measuring instrument on which only legally relevant software is located. The measuring instrument possesses only one user interface consisting of an integrated display with an integrated keyboard.

For the specific use case of interacting with the measuring instrument using the keyboard, section 1.5 “Protection of indication of the measurement result“ from Guide 7.6 needs to be considered. Also, the corresponding table from the annex to WELMEC Guide 7.6 [4] needs to be filled out (see *Figure 2*). The subsection 1.5.1. “Through other software” can be skipped here, since only legally relevant software is available on the example measuring instrument. Subsection 1.5.2 “Through user interface” addresses the specific threats through the user interface.



1.5 Protection of indication of the measurement result

This point correspond to chapter **3.4.1.5** of this Guide. (Adequate protection is the only child node).

1.5.1 Through other software

Threat nr.	Asset nr.	Asset	Countermeasure	Break down threat	Passed / Failed	Remarks
T.5	5	**Indication**				
T.5.1		Inadmissible influence **Through other software**				*n.a., only legally relevant software*
T.5.1.1		**Adequate protection with respect to**				
T.5.1.1.1		Availability				*n.a.*
T.5.1.1.2		Integrity				*n.a.*
T.5.1.1.3		Authenticity				*n.a.*

1.5.2 Through user interface

Threat nr.	Asset nr.	Asset	Countermeasure	Break down threat	Passed / Failed	Remarks
T.5	5	**Indication**				
T.5.2		Inadmissible influence				
T.5.2.1		**Adequate protection with respect to**				
T.5.2.1.1		Availability	*Inputs made via the keyboard through the legally relevant software are filtered using by a whitelist. Only listed and documented commands for Interpretation further passed that the display of the measured value does not influence.*	*An attacker tries with inputs about the keyboard, to suppress the measured value on the display or to move this in the background.*		*See list of commands in XXXX*
T.5.2.1.2		Integrity	*Inputs made via the keyboard through the legally relevant software are filtered using by a whitelist. Only listed and documented commands for Interpretation are further passed that not affect the reading.*	*An attacker tries with inputs about the keyboard to change the amount or the unit of the displayed measured value.*		*See list of commands in XXXX*
T.5.2.1.3		Authenticity	*Inputs made via the keyboard through the legally relevant software are filtered using by a whitelist. Only listed and documented commands for interpretation passed on. No command can be in the for measured values provided write screen area.*	*An attacker tries with inputs about the keyboard to generate a fake one a measured value.*		*See list of commands in XXXX*

Figure 2: List of generic threats for software with high-level attack vectors from Annex I in with an example

Columns 1 to 3 do not need to be edited as these are reserved for the threat ID, references to the requirements of WELMEC 7.2 Software Guide [6], and the asset name and its associated security property as specified by the WELMEC Guide 7.6 [4]. Columns 4 and 5 must be filled in: Columns 5 of the table illustrates various conceivable realizations of the threat for the example measuring instrument, such as the suppression of the measured value display (see T.5.2.1.1), the change in the measured value (see T.5.2.1.2) or the generation of faulty readings (see T.5.2.1.3). Each possible threat is assigned to the respective security property (Availability, Integrity or Authenticity). In column 4 a corresponding countermeasure realized in the measuring instrument should be listed for each individual threat. Column 6 must remain empty, this column is intended for comments for the conformity assessment body. Column 7, on the other hand, can be used for own comments.

Annex B: Tables

Elapsed Time	Points
less than 1 day	0
less than 1 week	1
less than 2 weeks	2
less than 1 month	4
less than 2 months	7
less than 3 months	10
less than 4 months	13
less than 5 months	15
less than 6 months	17
more than 6 months	19

Window of opportunity	Points
Unnecessary/unlimited access	0
Easy	1
Moderate	4
Difficult	10
None	**

**If access to the measuring system is impossible due to time constraints, the associated attack scenario does not need to be evaluated.

Required Expertise	Points
Layman	0
Proficient	3
Expert	6
Multiple expert	8

Equipment	Points
Standard	0
Specialized	4
Bespoke	7
Multiple bespoke	9

Knowledge of the measuring system	Points
Public	0
Restricted	3
Sensitive	7
Critical	11

Annex C: Exemplary risk analysis of an instrument-specific threat

In the following example, a measuring instrument based on a universal computer is examined, which contains a legally relevant storage unit for recorded measurement data. The storage shall be implemented as a text file that can only be read and written by the legally relevant application. The access control to the text file shall be implemented by operating system means, and the operating system itself shall be protected by a secret administrator password (here: 4 digits). Therefore, one possible attack on the availability of the stored measurement results consists of a user trying random password combinations until he or she has gained access to the system. With the acquired access rights, the user can then delete the text file. The assumed measuring instrument shall be available to the user without restrictions. In this described example, the asset to be protected is the storage of measurement results, and the associated security property is availability.

Threat

The user with normal access privileges invalidates the availability of the record of the measurement results.

Attack scenario

The user guesses correctly the administrator password by trying arbitrary four-digit combinations. Afterwards, the user deletes the text file.

Evaluation

- **Elapsed time:** There are 10^4 = 10,000 different possible four-digit passwords. Assuming that entering and validating a password lasts a maximum of 10 seconds, all 10,000 combinations can be tested in 100,000 seconds = 27.78 hours = 1.15 days. Even if an attacker only tries combinations for 4 hours per day, he or she won't need longer than 1.15×24/4 = 6.9 days. On average, the correct combination will be found after trying half of the possible passwords, e.g. after 3.5 days. In any case, the search for the correct password will not take longer than a week. The point score to be selected is, therefore, 1.
- **Expertise:** No special knowledge is required to guess a digit combination and delete a text file. Accordingly, even a layman could be considered a likely attacker, and 0 points for expertise are given.
- **Knowledge of the measuring system:** In a first step, the attacker needs to identify where the records of the measurement results are stored on the system and that they can be deleted or modified only after entering the administrator password. In the case of most operating systems, however, simply finding the file will suffice, since the user will be asked for the administrator password when trying to open the file. Consequentially only restricted knowledge of the system is required. The point score to be assigned is therefore 3.
- **Window of opportunity:** because the user is a possible attacker with unlimited access to the instrument, without the risk of being detected, the respective point score must thus be 0.
- **Equipment:** No equipment is needed for the attack (0 points).

Table 3: Evaluation of the example

Threat	Attack scenario	Elapsed time	Expertise	Knowledge of the measuring system	Window of opportunity	Equipment	Sum	Probability score	Impact	Risk
The user with normal access privileges invalidates the availability of the record of the measurement results.	The user guesses correctly the administrator password by trying arbitrary four-digit combinations. Afterwards, the user deletes the text file.	1	0	3	0	0	4	5	1	5

Since the described threat could affect all past measurements, the impact must be set to 1. Consequentially, the risk is identical to the calculated probability score, after multiplying impact and probability score.

Consequences

As a general rule, all threats with a risk of 4 or 5 must be mitigated by technical or organizational measures until, after a new assessment, a risk in the range between 1 and 3 is reached. In the presented example, an adjustment of the password length to 6 digits (100 times more combinations than for 4 digits) would result in point score of 19 for elapsed time (3.5 days * 100 = 350 days). This would virtually eliminate the threat of an attacker guessing the correct password.