

Section 1 Scope

The following Release Notes apply to the SPRECalc applications for SOLID and FLUID samples, developed by the Integrated BioBank of Luxembourg (IBBL) to facilitate the tracking of SPREC values for biospecimens.

The tool is based upon the SPREC v2.0 (publication in preparation).

SPRECalc application	Version	File Type
SOLID samples	V1.0	Excel Macro-enabled Workbook (.xlsm)
FLUID samples	V1.0	Excel Macro-enabled Workbook (.xlsm)

IBBL shall not be held responsible for errors in SPREC allocation to samples by the use of this tool; especially, when changes to the published version have been made by the users or when customer's environment does not support the security features available in the files.

Section 2 Technical Information

2.1. Development Environment

The Excel files (.xlsm) have been developed and tested in the following environment:

- PC Workstation
- Windows 7 Professional, Service Pack 1
- Microsoft Office Professional Plus 2010
- European Setting (e.g. French)

The same operating system, software version and settings should be used to ensure that all features of the files work properly.

2.2. Settings

2.2.1. Date/Time

Parts of the worksheet, especially the Date/Time fields are preformatted to allow automated calculations of time spans.

Therefore it is mandatory to ensure that the workstations, on which the Excel Files are run, are configured for European Settings; especially ensuring that date/time stamps are displayed as dd/MM/yyyy HH:mm.

2.2.1.1. How to change the settings?

Please refer to Annex 1 of this document.

2.2.2. Security

In order to support homogeneous data entry, drop down lists are implemented, so that no other entries than the predefined list values can be entered.

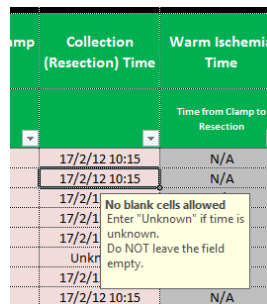
However, in configuration settings, which are not compliant with the development environment (see § 2.1), the protection may not work.

It is recommended to check this for each workstation, where the Excel files are used. Eventually allow data entry only on workstations, which support the implemented data protection features.

2.2.3. Data Validation Rules

In order to provide ad-hoc information about data entry rules as described below in §§ 3.2.2 and 4.2.2, in relevant fields comments are displayed, once the user clicks on the field.

Example:



Clamp	Collection (Resection) Time	Warm Ischemia Time
	17/2/12 10:15	N/A
	17/2/12 10:15	N/A
	17/2/1	
	17/2/1	
	17/2/1	
	Unkn	
	17/2/1	
	17/2/12 10:15	N/A

Please follow the instructions displayed in the message box to ensure proper functioning of the SPREC calculation.

2.2.4. Initial Data Set

The provided SPRECalc files for SOLID and FLUID samples are pre-filled with arbitrary data, in order to demonstrate the principle of the system. These data should be deleted in the version you make available to your users.

2.2.5. Implementation of the SPRECalc tools

It is recommended that each organization names an “administrator” of the SPRECalc files, who should be experienced with the use of MS Excel. The administrator should customize the files and ensure password protection of worksheets, where needed, before providing the tool to users for data entry.

User’s should perform data entry on workstations that comply with specifications in § 2.2.2. They should NOT know passwords to unprotect protected worksheets in the files.

To use the files in your organization:

- Download the files on a computer.
- Delete the example data in worksheet.
- Customize worksheets, where required, according to the needs of your organization.
 - NOTE: The worksheets “SPREC-calculation”, “Lists” and “Statistics” are password protected by IBBL and cannot be customized.
- Save the customized files with an appropriate name and version in your organization; allowing access to the files according to your access policies.
 - NOTE: Consider preparing one dedicated file for each sample collection/study.
- Perform data entry only on workstations, which support the implemented security functionalities (see § 2.2.2).
- Save the file after each update (or according to your organizations’ specifications).

Section 3 SPRECalc SOLID

3.1. Workbook Composition

3.1.1. “SPREC Calculation” Worksheet

This worksheet is used to track pre-analytical information for solid biospecimens; by completing one full row for each sample, the tool provides a completely automated summary of the variables in form of the 7-element long SPREC as defined in the relevant publications.

This worksheet is password protected by IBBL to ensure that no changes to the logical parts of the worksheet can be made by users.

3.1.2. “Fixation Programs” Worksheet

This worksheet can be used optionally, in order to define automated fixation programs, especially the duration of fixation.

If applicable, during data entry in the “SPREC calculation” worksheet, this information is retrieved and can so make the data entry more efficient and flexible.

This worksheet is protected. However, it can be unprotected to customize the data for the users’ organization. It is highly recommended to protect the worksheet with a password, once the customization took place.

3.1.2.1. How to protect worksheets in Excel?

Please refer to Annex 2 at the end of this document

3.1.3. “Lists” Worksheet

Here are all specifications as per SPREC v2.0 – Table 2 (for solid samples) documented; some of this information is “translated” in help tables to allow the automated allocation of SPREC values.

This worksheet is password protected by IBBL to ensure that no changes to the specifications of the SPREC can be made by users.

3.1.4. “Statistics” Worksheet

In this part, some summary statistics are provided for information.

This allows availability of “real-time” statistics about the characteristics of the collection.

This worksheet is password protected by IBBL to ensure that no changes to the specifications of the statistics can be made by users.

This worksheet is an optional tool and does not impact on the automated SPREC calculation; however, it uses all the data that are entered in the “SPREC calculation” worksheet.

3.1.5. “KPI” Worksheet

“KPI” stands for Key Performance Indicators. KPIs are used in Quality Management to define and track fulfillment of quantitative or qualitative requirements (e.g. quality objectives) in a measurable manner.

This worksheet contains some examples how KPIs can be customized for your organization, allowing “real-time” tracking of important parameters of your collection.

The worksheet is protected. It can be unprotected to define your parameters according to your specifications.

This worksheet is also an optional tool and does not impact on the automated SPREC calculation.

3.1.5.1. How to protect worksheets in Excel?

Please refer to Annex 2 at the end of this document

3.1.6. “NonConformities” Worksheet

This worksheet provides a 1:1 copy of selected data (Sample ID and SPREC) from the “SPREC-calculation” worksheet as they have been entered.

It is intended to program the automatic detection of non-conformities of samples (according to your specifications), by using the “Conditional Formatting” option of MS Excel.

DO NEVER ENTER DATA IN THIS WORKSHEET.

The worksheet is NOT protected by IBBL in order to allow configuration of your specification; nevertheless, it is strongly recommended to protect the worksheet against any changes by users, once the configuration has been completed.

If required, this worksheet may also be used to create customized statistics as needed.

3.2. Data Entry Rules for the “SPREC Calculation” Worksheet

3.2.1. Color Codes

Field Characteristics	Rules
Blue fields	Data entry by selection from drop down lists only (no other values allowed – provided provisions of § 2.2.2 are fulfilled)
White fields	Free data entry
Pink fields	Entry of Date/Time in format dd/MM/yy HH:mm NOTE: fields are pre-formatted for European date/time settings, so that an entry of e.g. 24/2 17:35 [for the 24 February 2012, 17h35 (or 5:35pm)] results automatically in the correctly displayed timestamp, i.e. 24/02/2012 17:35 Make sure that your workstation configuration is set to European display of date/time stamps as specified in Annex 1.
Grey fields	Calculated values (not accessible for users)
SPREC	Calculated values – automatically filled as data entry progresses for each sample row (not accessible for users, i.e. no manual “overriding” is possible)
1st Line of “SPREC calculation” Worksheet (black background)	Used to document (and applied for calculations of) user-defined criteria to support automated QC checks, i.e. detection of non-conformities. In the basic tool, the automatic detection of fixation time > 24h is pre-programmed in 2 ways: <ul style="list-style-type: none"> As separate column beside the “Fixation Time” column. By means of conditional formatting, for samples, which pass the limit of 24h for fixation time, the code NC (for “non-conformity”) is displayed automatically In the “Fixation Time” column of the SPREC summary, again by means of conditional formatting, all samples which have fixation times >24h, or fulfill the “unknown” or “other” condition, are highlighted with red background. The use of this option is not required for automated SPREC calculation. It is programmed as example only.

3.2.2. Field Entries

Field Name	Data Entry Requirements*
General	Avoid “copy & paste” data entry <u>across</u> columns, since it might affect the correctness of the calculation “Copy & paste” may be used <u>within</u> columns (e.g. to copy the start time of a centrifugation down to all samples of the same batch).
Vascular Clamp Time	“N/A” is mandatory for all Collection Types, which are NOT surgical excision related
	“Unknown” is mandatory, if the time is unknown
	No blank fields are accepted (i.e. the SPREC calculation does not work)
Collection (Resection) Time	“Unknown” is mandatory, if the time is unknown
	No blank fields are accepted (i.e. the SPREC calculation does not work)
Fixation Start Time	“Unknown” is mandatory, if the time is unknown
	No blank fields are accepted (i.e. the SPREC calculation does not work)
Fixation – Option 1 Automated Fixation Process is used for the sample:	
Fixation Program Start Time	Entry of Date/Time in format dd/MM/yy HH:mm (see comments in § 3.2.2 and Annex 1)
Fixation Program Type	Select a program from the list (The program must be pre-defined in the “Fixation Programs” Worksheet, refer to § 3.1.2)
Fixation End Time (non-automated process)	Leave the field empty
Fixation – Option 2 Non-Automated Fixation Process is used for the sample:	
Fixation Program Start Time	“N/A” is mandatory
Fixation Program Type	Leave the field empty
Fixation End Time (non-automated process)	Entry of Date/Time in format dd/MM/yy HH:mm (see comments in § 3.2.2 and Annex 1)
Container Type & Long-term Storage (LTS) Temperature	Select items form the drop down lists. NOTE: The system automatically concatenates the values and compares it against the defined SPREC values; in case a “non-valid” combination is entered, the system puts the variable “Z” for “Other” in the SPREC summary; in the case, one of the two values is “Unknown”, the SPREC summary is filled with the code “X”.

* “ ” are used for better readability in this text; do not enter into Excel.

Section 4 SPRECalc FLUID

4.1. Workbook Composition

4.1.1. “SPREC Calculation” Worksheet

This worksheet is used to track pre-analytical information for fluid biospecimens; by completing one row for each sample, the tool provides a completely automated summary of the variables in form of the 7-element long SPREC as defined in the relevant publications.

This worksheet is password protected by IBBL to ensure that no changes to the logical parts of the worksheet can be made by users.

4.1.2. “Lists” Worksheet

All specifications as per SPREC v2.0 – Table 1 (for fluid samples) – are documented here; some of this information is “translated” in help tables to allow the automated allocation of SPREC values.

This worksheet is password protected by IBBL to ensure that no changes to the specifications of the SPREC can be made by users.

4.1.3. “Statistics” Worksheet

In this part, some summary statistics are provided for information.

This allows availability of “real-time” statistics about the characteristics of the collection.

This worksheet is password protected by IBBL to ensure that no changes to the specifications of the statistics can be made by users.

This worksheet is an optional tool and does not impact on the automated SPREC calculation; however, it uses all the data that are entered in the SPREC-calculation worksheet.

4.1.4. “KPI” Worksheet

“KPI” stands for Key Performance Indicators. KPIs are used in Quality Management to define and track fulfillment of quantitative or qualitative requirements (e.g. quality objectives) in a measurable manner.

This worksheet contains some examples how KPIs can be customized for your organization, allowing “real-time” tracking of important parameters of your collection.

The worksheet is protected. It can be unprotected to define your parameters according to your specifications.

This worksheet is also an optional tool and does not impact on the automated SPREC calculation.

4.1.4.1. How to protect worksheets in Excel?

Please refer to Annex 2 at the end of this document

4.1.5. “NonConformities” Worksheet

This worksheet provides a 1:1 copy of selected data (Sample ID and SPREC) from the “SPREC-calculation” worksheet as they have been entered.

It is intended to program the automatic detection of non-conformities of samples (according to your specifications), by using the “Conditional Formatting” option of MS Excel.

DO NEVER ENTER DATA IN THIS WORKSHEET.

The worksheet is NOT protected by IBBL in order to allow configuration of your specification; nevertheless, it is strongly recommended to protect the worksheet against any changes by users, once the configuration has been completed.

4.2. Data Entry Rules for the “SPREC Calculation” Worksheet

4.2.1. Color Codes

Field Characteristics	Rules
Blue fields	Data entry by selection from drop down lists only (no other values allowed – provided provisions of § 2.2.2 are fulfilled)
White fields	Free data entry
Pink fields	Entry of Date/Time in format dd/MM/yy HH:mm NOTE: fields are pre-formatted for European date/time settings, so that an entry of e.g. 24/2 17:35 [for the 24 February 2012, 17h35 (or 5:35pm)] results automatically in the correctly displayed timestamp, i.e. 24/02/2012 17:35 Make sure that your workstation configuration is set to European display of date/time stamps as specified in Annex 1.
Grey fields	Calculated values (not accessible for users)
SPREC	Calculated values – automatically filled as data entry progresses for each sample row (not accessible for users, i.e. no manual “overriding” is possible)

4.2.2. Field Entries

Field Name	Data Entry Requirements*
General	Avoid “copy & paste” data entry <u>across</u> columns, since it might affect the correctness of the calculation. “Copy & paste” may be used <u>within</u> columns (e.g. to copy the start time of a centrifugation down to all samples of the same batch).
Collection Time	“Unknown” is mandatory, if the time is unknown
Pre-centrifugation Delay (calculated field)	Values, which do not correspond to SPREC definitions are displayed as error values and “translated” into “X” for “Unknown”
1. Centrifugation Start Time	“Unknown” is mandatory, if the time is unknown For PAXgene tubes enter the start time of freezing at about -20°C
1. Centrifugation Temperature	By convention , select “No centrifugation” from the drop down list, when no 1st centrifugation is performed
1. Centrifugation End Time (calculated field)	If no value can be calculated from the entered data, an error value is displayed and “translated” into “X” for “Unknown”
2. Centrifugation Start Time	“Unknown” is mandatory, if the time is unknown For Viable Cells enter the start time of the last washing centrifugation
2. Centrifugation Temperature	By convention , select “No centrifugation” from the drop down list, when no 2nd centrifugation is performed
2. Centrifugation End Time (calculated field)	If no value can be calculated from the entered data, an error value is displayed and “translated” into “X” for “Unknown”
Post-centrifugation Delay (calculated field)	Values, which do not correspond to SPREC definitions are displayed as error values and “translated” into “X” for “Unknown”
Container Type & LTS Temperature	Select items form the drop down lists. NOTE: The system automatically concatenates the values and compares it against the defined SPREC values; in case a “non-valid” combination is entered, the system puts the variable “Z” for “Other” in the SPREC summary; in the case, one of the two values is “Unknown”, the SPREC summary is filled with the code “X”.

* “ ” are used for better readability in this text; do not enter into Excel.

Section 5 Quality Control Features

The SPRECalc files allow efficient plausibility check of data entries, e.g. by display of “error” messages in calculated fields like in the example below.

Data display like “#####”, “N/A” or “#REF” in calculated fields may occur under two circumstances:

- Not all data, necessary to complete the calculation, have been entered in the row of the sample.
- The data entry for the sample row is complete, but wrong.

Example:

The Fixation Start Time is BEFORE the Collection (Resection) Time, which is not plausible.

Collection (Resection) Time	Warm Ischemia Time	Cold Ischemia Time	Fixation / Stabilization Type	Other Type of Fixation / Stabilization	Fixation Start Time
Time from Clamp to Resection	Time from Clamp to Resection	Time from Collection to Fixation Start			Time into Fixation Medium
17/2/12 10:15	N/A	2:17:00	Alcohol-based		17/2/12 12:00
17/2/12 10:15	N/A	#####	Aldehyde-based		16/2/12 12:32
17/2/12 10:15	N/A	2:17:00	Allprotect tissue reagent		17/2/12 12:32
17/2/12 10:15	N/A	2:17:00	Heat stabilization		17/2/12 12:32

If you detect data like “#####” or “N/A” or “#REF” in calculated fields resulting in erroneous or unplausible SPREC values, do the following:

- Verify if the data entry for the samples has been fully completed for the given sample:
 - If all data have been fully completed, check plausibility of dates relevant for the calculated field and/or re-verify relevant data entries against raw data
 - If not all data have been completed, complete all data and check, if error persists.
 - If error is no longer displayed, data entry is plausible.
 - If error persists, check plausibility of dates relevant for the calculated field and/or re-verify against raw data.

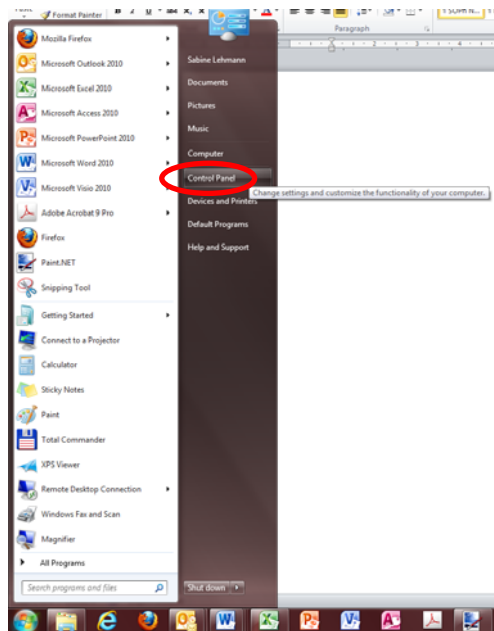
Regular QC checks for plausibility can also be made by using the “Filter” functionalities of Excel. However, the normal limitations of Excel with respect to use of filters have to be considered (please refer to the HELP function in MS Office for further information).

Annex 1: How to make Date/Time settings

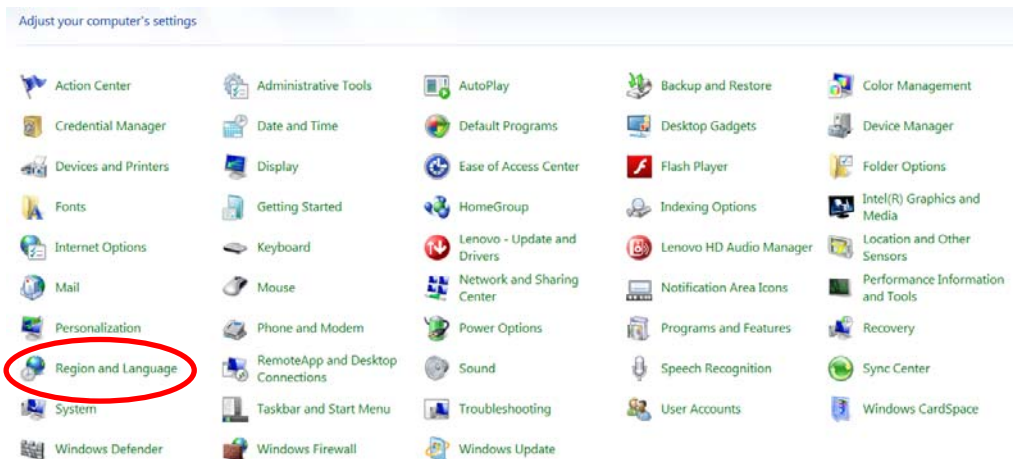
- Ensure that you are working with:
 - Windows 7 Professional, Service Pack 1 and
 - Microsoft Office Professional Plus 2010
- Click on the Start button located in the bottom of your display:



- Click on the Control Panel option.

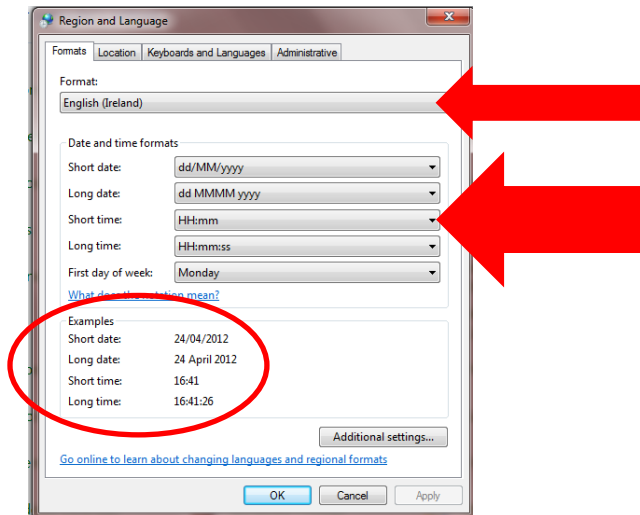


- Select the Region and Language option



- Enter settings, which correspond to the specifications below.

In the “Format” field, select any European format, because the default settings for Date and time formats would comply in most cases with the requirements for the use of SPRECalc V1.0.



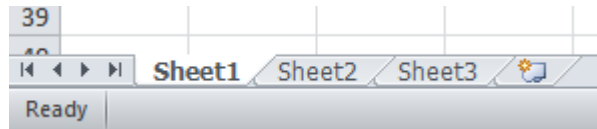
It is important that the dates are displayed in DAY/MONTH/YEAR format and that time is set using the 24h clock.

When having made your settings, verify if the displayed example values correspond to the values shown in this screenshot.

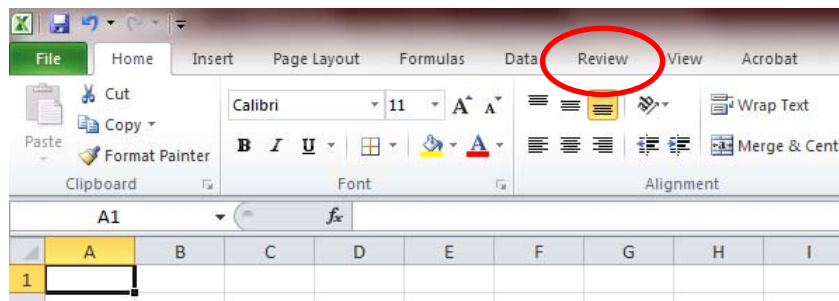
Annex 2: How protect/unprotect a Worksheet

A – Protect a Worksheet with a Password

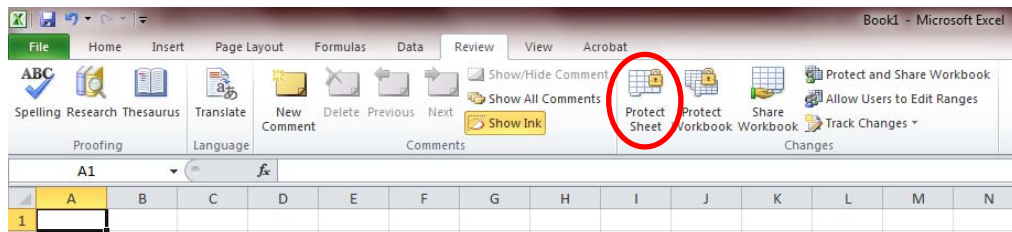
1. Go into the Worksheet that shall be protected.



2. Select the Review tab in the upper toolbar.



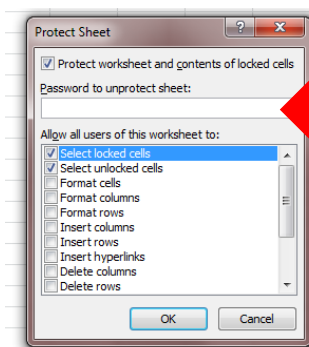
3. Select the Protect Sheet option in the upper toolbar.



4. The “Protect Sheet” window appears.

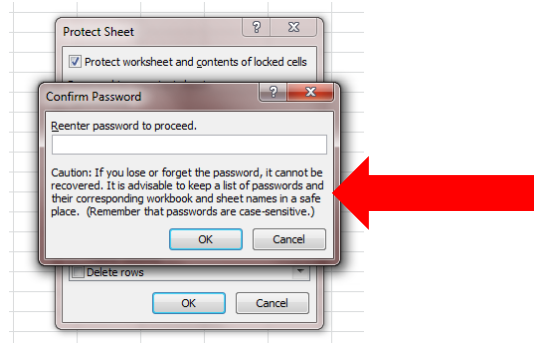
Enter a password to protect the sheet and select the actions the users shall be allowed to be performed in the protected worksheet.

Click on OK, when all entries have been made.



- The “Confirm Password” window appears.

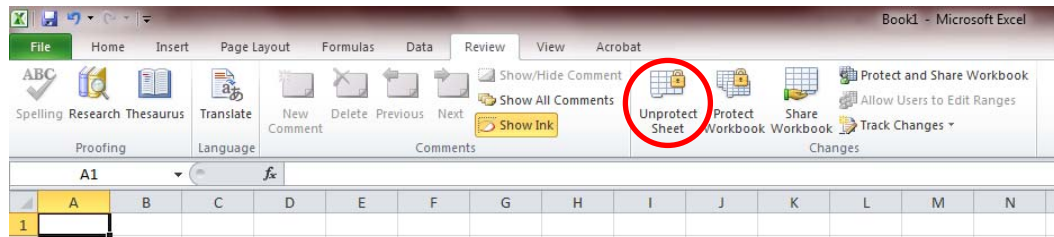
Re-enter the password and click on OK. NOTE: Take the warning in the displayed box seriously.



- Save the file, once the password protection has been implemented.

NOTE: The protection becomes only effective, once the file has been saved.

A (password) protected Worksheet can be recognized by the “Unprotect Sheet” display in the Review toolbar:



B – Unprotect a password-protected Worksheet

- Go into the Worksheet you want unprotect.
- Select the Review tab in the toolbar.
- If the toolbar displays the “Unprotect Sheet” option (see above), the Worksheet is protected.
- Click on the “Unprotect Sheet” option.
- The “Unprotect Sheet” window appears. Enter the password, used to protect the Worksheet before (steps 4 and 5) and click on OK.
- The Worksheet is now unprotected.

C – Protect/unprotect a Worksheet without password

- To protect a Worksheet without password, perform the actions as described in Part A, but do NOT enter a password in step 4.
- To unprotect a Worksheet protected without password, perform the actions 7 to 10. The Worksheet is immediately unprotected.