

# ExcelKontrol *Light* 1.0

Software for Control Charts

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The author has developed this software and manual to the best of his knowledge.

Nevertheless he will not accept any warranty for certain properties and no liability for damages caused by the use of this program.

**Improvement of the program**

If you have proposals for the improvement or if you found any mistakes, please contact the author. Your help will be highly appreciated.

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## 2 Introduction

Control charts are powerful tools for internal quality control in the analytical laboratory. So control charts are widely used and required by international standards such as ISO/IEC 17025.

**This manual is not intended to replace the use of a good textbook or the attendance of a suitable seminar.**

ExcelKontrol *Light* is a simple Excel® tool conceived for the daily use of X control charts in laboratories.

The full version of ExcelKontrol may be obtained from [www.aqsbw.de](http://www.aqsbw.de). With the full version also other control charts like range control charts can be made and you can make more adjustments in X control charts.

This software is based on the description of control charts in Funk, W., Donnevert, G. and Dammann V. 2006. Quality Assurance in Analytical Chemistry. 2nd edition Wiley-VCH, Weinheim

## 3 System requirements , macro security

Microsoft Excel 2007/2010 and later.

When starting the program you may get a security warning, noting that some active content has been disabled. By clicking the button “options” you may activate the macros. Otherwise the program will not work. If you select “Trust all documents from this publisher”, no blocking will happen in future for ExcelKontrol.

If you want to permanently allow execution of all Macros click the Microsoft Office Button, and then click Access Options. Click Trust Center, click Trust Center Settings, and then click Macro Settings.

## 4 Theoretical background

Control charts are a statistical tool for the control of a process such as an analytical determination. They deliver warning and alarm signals if the probability is high that the process is out-of-control. There are plenty of different publications on the use of control charts, but there is no prescription on the use of quality criteria and rules for out-of-control-situations. We used the above mentioned literature to select rules.

Control charts were first introduced by Shewhart. He measured a parameter of a product in order to recognize changes in the production process as soon as possible.

Later this technique was transferred into analytical chemistry in several types of charts. For more information about different charts see the above mentioned literature (chapter 2).

X-charts (mean charts) are the charts which are similar to the original Shewhart chart. A control sample which has to be stable over a long time period is measured once whenever the respective analyte is measured in the laboratory. So usually we will get one value per day. This value is plotted and in time we get a scatter plot around a mean value. X-charts deliver information about the precision of the analysis under intermediate conditions and changes in the trueness. If samples are used for which a good estimate of the true value is available (e.g. reference materials) and that are similar in matrix to routine samples an assessment of trueness is also possible.

### 4.1 Warning and action limits

#### 4.1.1 General

Action limits form the boundaries of a range, within which the result of a measurement is expected with a certain probability. If a  $\pm 3s$ -range is used as action limits (which is quite common) this probability is 99.7%. Since the probability that a value outside these limits is still a correct result is very low, such a result indicates that an immediate action is required.

Warning limits give a warning signal only, indicating that a value is close to the action limit, but still didn't reach it. More than one value outside the warning limits within a short period of time could also indicate a problem in the process. If a  $\pm 2s$ -range is used as warning limits (which also is quite common) the probability that a result is outside this range is 95.5%.

The use of target limits, deviated from external requirements on the analysis, is possible only with the full version of ExcelKontrol.

#### 4.1.2 Statistical calculation of warning and action limits

If the warning and action limits are statistically calculated, a pre-period is needed to gain the necessary data. During this pre-period the control samples shall be measured under completely the same conditions as during the following control period. If e.g. during the control period the control sample is measured once per day, the same shall be done during the pre-period.

## 4.2 Out-of-control situations

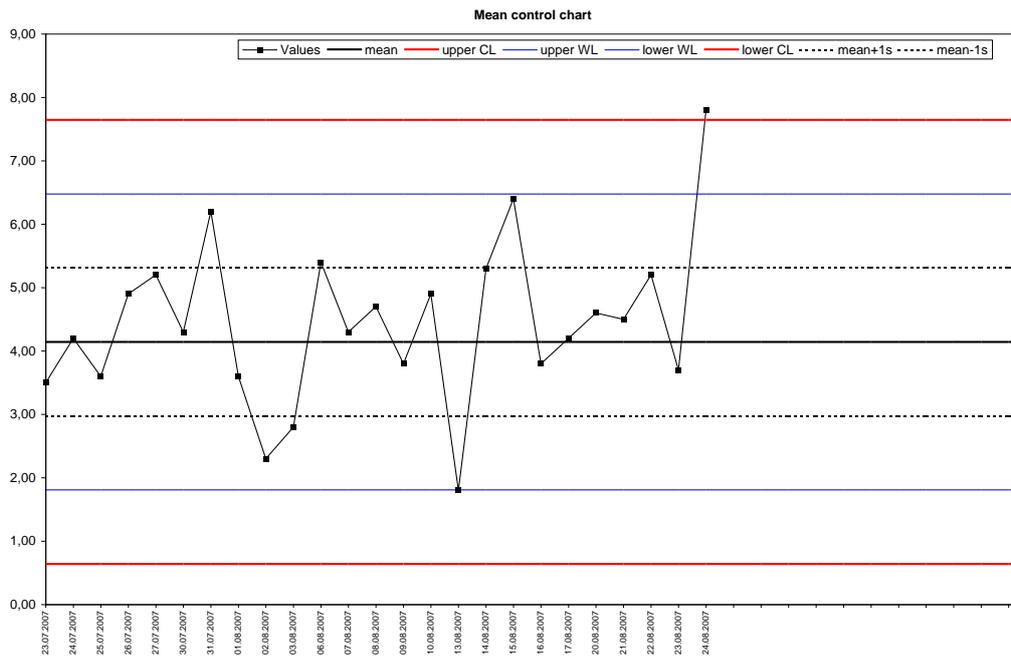
### 4.2.1 General

Out-of-control situations indicate that a situation has occurred which is unlikely to happen with normal distributed data sets.

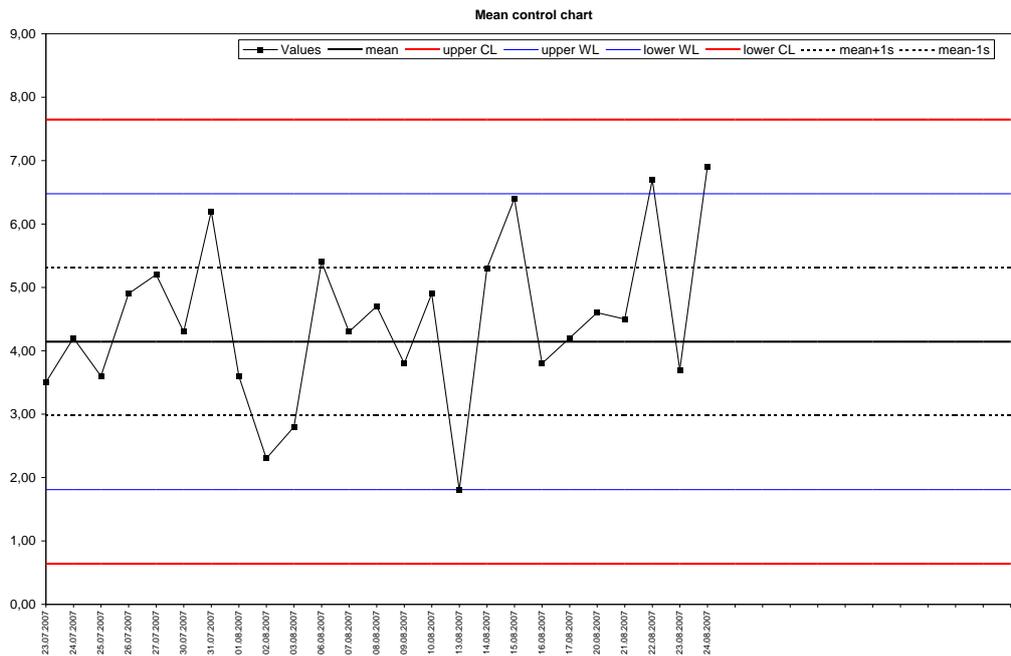
### 4.2.2 Different types of out-of-control situations

#### 4.2.2.1 Out-of control situation A - One value beyond control limits

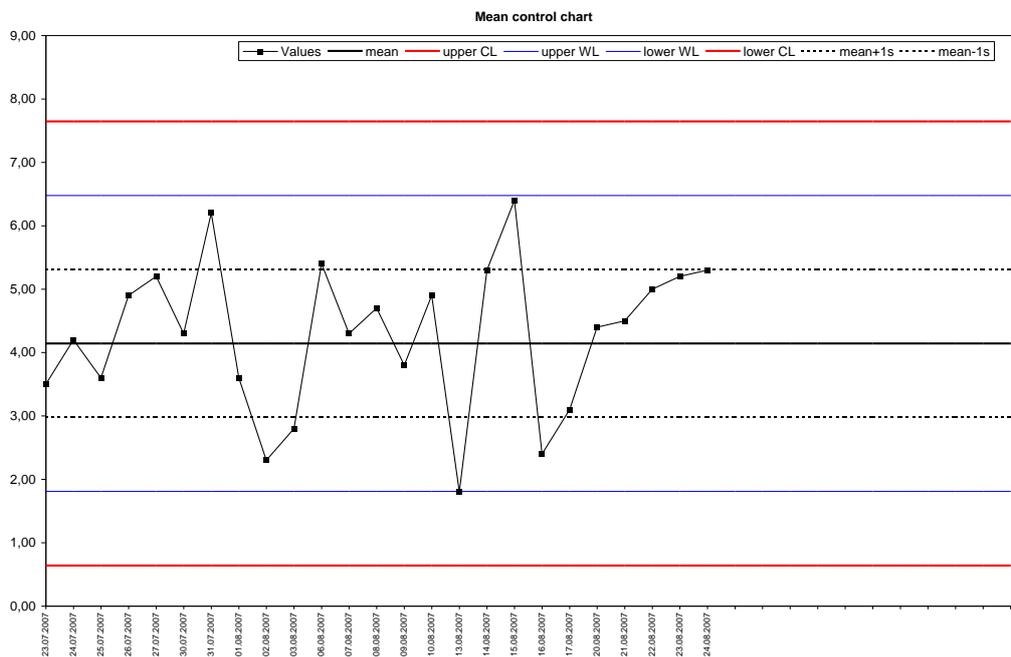
If a measurement results falls outside the control limits the process immediately is out of control.



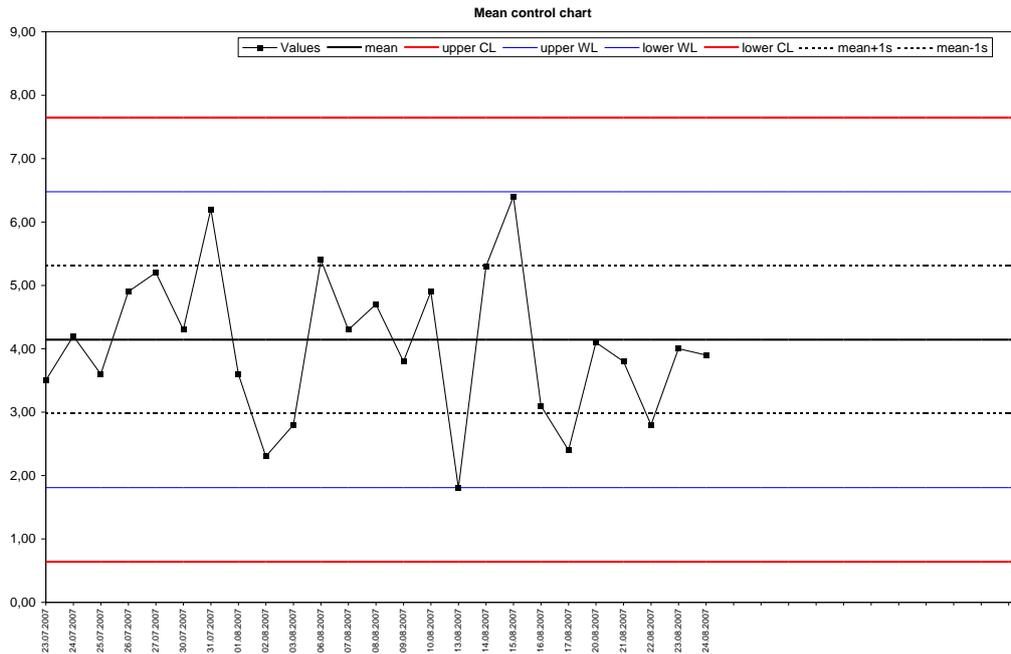
### 4.2.2.2 Out-of-control situation B – Two out of three successive values beyond warning limits



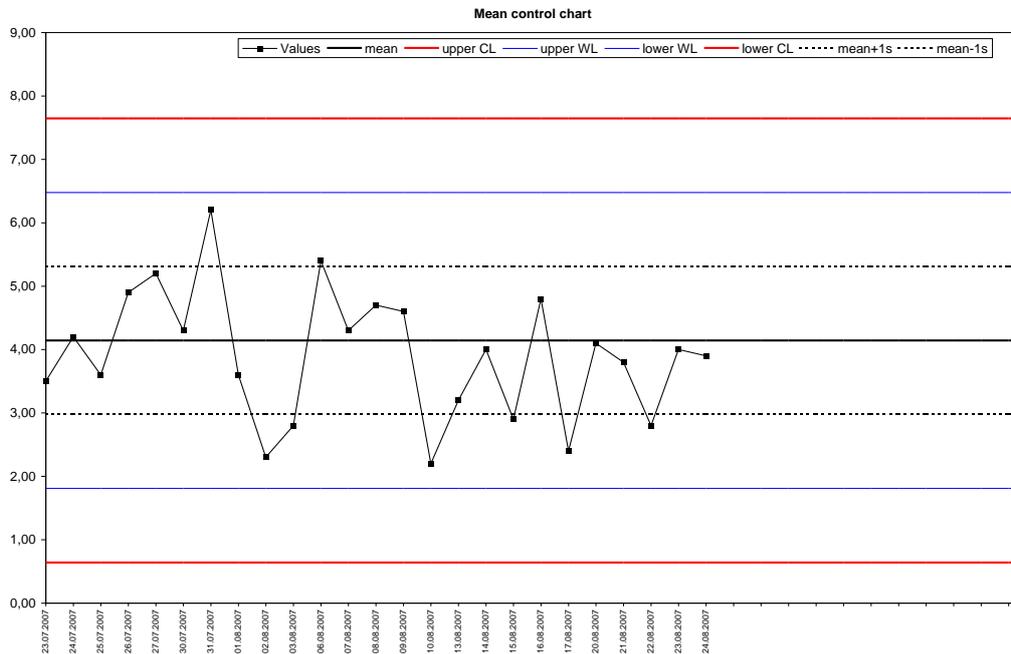
### 4.2.2.3 Out-of-control situation C – Seven values in a row steadily increasing or decreasing



#### 4.2.2.4 Out-of-control situation D – Seven values in a row on the same side of the central line



#### 4.2.2.5 Out-of-control situation E – Ten out of eleven values in a row on the same side of the central line



### 4.2.3 How to react to out-of-control situations

As mentioned above out-of-control situations just indicate an unlikely situation. Therefore the first action is to stop the analytical process and to look for the reason for this situation. If possible actions have to be taken to remove the cause of the out-of-control situation. It is always necessary to look at the situation with a common sense and to decide on the background of the analytical experience. In some cases the deviation may be statistically significant, but inessential to the intended purpose of the analysis. In this case no action may be necessary. In any other cases it is up to the analyst to decide about the necessary action and documentation is required for all kind of actions taken after an out-of-control situation. For more information please consult relevant textbooks.

## 5 General structure of the programme sheets

### 5.1 General

Activate the "data"-sheet if necessary. You may write into all white cells. You cannot change gray and yellow cells.

It is possible to insert more than 100 data. As soon as you entered the 100th value and you press "Check" there will be 100 more fields.

For statistical calculations at least 12 data have to be entered for the pre-period. Only then warning and control limits can be calculated.

Below the box with statistical data and the calculated limits you find a button to clear all control period data. This button can be used to start a new control chart with the same limits.

In the "Plot"-sheet you will find the graphical display of the control period, the actual control chart.

### 5.2 Header

In the header of each sheet you may indicate general information about the respective control chart such as parameter, matrix, unit, operator etc. Part of these data will be transferred to the header of the plot.

### 5.3 Pre-period data

For the calculation of warning and action limits from the pre-period, the columns on the left side are used. Please enter the date together with the result of the analysis. At least 12 values are necessary for the statistical calculations. The results of these calculations are shown in the statistics box at the right side.

### 5.4 Control-period data

The results during the control period are entered into the cells in the middle of the sheet (also together with the date).

**After entering the result press one of the "Check"-buttons to check for out-of-control-situations that are indicated in the gray cells.** All buttons do the same thus only click once.

You may use the white cell on the right to add comments (e.g. actions after out-of-control situations).