

# **INFUSCALE**

**Version 8**

**User manual**

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## **Use of INFUSCALE**

INFUSCALE may only be used on one computer at a time. Copying, duplicating or passing on or selling INFUSCALE to third parties is not permitted. A backup copy may be made for the purpose of data backup.

## **Liability**

We make every effort to provide you with an error-free product. However, no guarantee can be given that the software will run without interruption or error in all situations and that the functions contained in the software can be executed in all combinations selected by you. Also no guarantee can be given for the achievement of a certain purpose of use, despite thorough program validation. Liability for damages of any kind in connection with the use of this program is excluded to the extent permitted by law.

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## 1 INTRODUCTION

The INFUSCALE program is used to precisely determine the delivery accuracy of infusion pumps and controllers using the gravimetric method. It runs on personal computers or notebooks on the operating systems Windows 2000, XP, 7, 8 and 10. An electronic scale is connected to the computer.

INFUSCALE has the following functions:

- Use together with electronic laboratory scales connected to a personal computer or notebook via a RS232 interface or a USB interface
- Acquisition of weighing data at adjustable time intervals
- Saving the weighing data as a file
- Graphical and numerical display of measurement data and event markers
- Evaluation according to the IEC60601-2-24 Edition 1:1998 or Edition 2:2012-10 standard
- Calculation and display of trumpet curves
- Editing the data with the skip function
- Copying edited INFUSCALE files to new files
- Calculation and display of trumpet curves with 31 observation windows (AAMI)
- Evaluation according to MDA Device Bulletin DB2003(02)
- Calculation of the constancy index
- Graphic display of weight and flow rate curves
- Graphics output as BMP and JPG files and saving to clipboard
- Display of values in tables and measurement logs
- Screen printout, table printout, measurement report printout
- Saving of the measurement report as Microsoft Word and Excel file as well as in the file formats TXT, WMF, HTML and CSV
- Saving the data as an EXCEL file
- Event marker storage

INFUSCALE has been used for 25 years in the testing of infusion pumps and has proven to be very reliable according to the state of science and technology. Files saved with previous INFUSCALE versions can also be read and evaluated by INFUSCALE 8.

## 1.1 Changes compared to previous version

- Evaluation optionally according to IEC60601-2-24 Edition 1:1998 or Edition 2:2012-10
- Extended evaluation option of the stored weighing data by means of the skip function
- Creation of file copies based on existing INFUSCALE files
- Optional display of trumpet curves also with 31 observation windows (AAMI)
- Evaluation of type 2 pumps now also with S less than 1 min
- In data acquisition mode, improved scaling and display of small values
- Pause function in data acquisition mode
- Eight instead of four selectable COM ports
- With the freely adjustable trumpet curve optionally 5, 6 or 31 observation windows
- Operation of scales that have a resolution of 1µg and 6 decimal places
- For the "Custom" scale, the "requ" request mode is now also possible
- Improved bolus evaluation
- In data acquisition mode, manual Y-scaling in the "Flow rate" graph.

## 1.2 General information on the infusion standard

The standardization work on the international standard concerning infusion pumps and infusion controllers was carried out by a working group of the IEC (International Electrotechnical Committee). The work was completed in 1998 with the publication of the standard IEC 60601-2-24 "Particular requirements for safety of infusion pumps and controllers", First edition 1998-02. In the same year, the standard was included as EN 60601-2-24:1998 in the list of standards harmonized in accordance with the European Medical Devices Directive 93/42/EEC.

In 2012, a new updated edition of IEC 60601-2-24 was published as Edition 2.0 under the title "Particular requirements for basic safety and essential performance of infusion pumps and controllers". However, IEC 60601-2-24:2012 is not yet harmonized according to the European Medical Device Directive 93/42/EEC.

The changes of edition 2.0 compared to the first edition of 1998 are realized in INFUSCALE version 8. It is possible to switch between the first and the second edition of the standard in the setup menu.

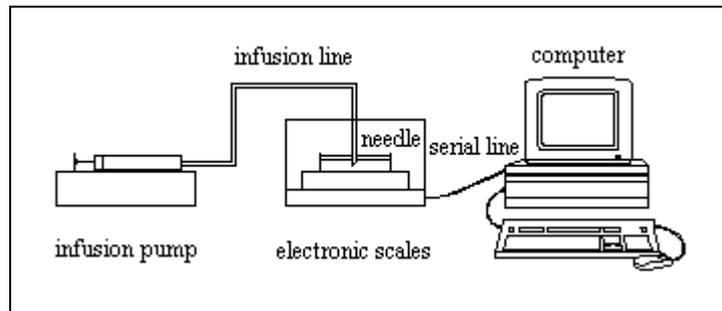
The task of this program is to perform and document the accuracy measurements together with the corresponding hardware (see Figure 1). This is of interest because the graphs described in the standard are an integral part of every infusion apparatus instruction manual.

In addition, INFUSCALE can also be used in the development and periodic review of infusion devices.

### 1.3 The gravimetric measuring method

The gravimetric method for determining the delivery accuracy of infusion pumps works with an electronic scales and a digital computer connected to it. The volume of fluid delivered by the pump under investigation is weighed at specific time intervals, the result is transmitted to the computer and evaluated by it.

Figure 1: Measurement setup



The measurement setup (Figure 1) corresponds to the specifications in Figures 201.104a and 201.104b of the IEC60601-2-24:2012-10 standard. The pump and measurement apparatus are set and started according to the pump type. The pump delivers the test liquid (water for medical use according to ISO class III, density 0.998g/mL at 20 °C) into the container located on the scale. The weight of the container increases in proportion to the volume of liquid pumped and is transmitted to the computer at regular intervals via an interface and stored there. The INFUSCALE menu item "Data Aquisition" , "Measurement", which is to be selected for this purpose, is called up and, after entering the test parameters, the measurement data acquisition is started.

#### Notice:

Testing of nutrition pumps must be performed with the nutrition liquid provided by the manufacturer. Before starting the measurement, the density of the nutrition fluid must be determined and entered in the field provided instead of the value of 0.998g/mL (water).

After the measurement is finished, the evaluation can be carried out according to the regulations of the standard or according to the user's requirements.

For INFUSCALE, the menu item "Evaluation" is called up in the main menu for this purpose.

For volumetric infusion controllers, volumetric infusion pumps and syringe pumps, the evaluation is very simple. In the "Evaluation" screen, after loading the file, it is only necessary to click on the **102** key to let the rest run automatically. A prerequisite for this, however, is a measurement duration of more than two hours, which corresponds to at least 241 measurement points with a measurement interval of 30s.

For the other pumps - e.g. pumps with bolus delivery or quasi-continuous delivery characteristics - a fully automatic evaluation is not useful. Here, the user is supported by various options for the evaluation.

The range of application of INFUSCALE with regard to the flow rate of the various pump systems is mainly determined by the weighing range and the reaction time to weight changes of the existing scale.

## 2 INSTALLATION

### 2.1 Equipment requirements

- Electronic scale with RS232 interface (uni- or bidirectional)
- A small selection of the scale types supported by INFUSCALE can be found in Table 1. More scales can be found on the website [www.infuscale.de](http://www.infuscale.de)
- PC with Windows 2000, XP, 7, 8 or 10 operating system
- Graphics screen with at least 800/600 pixel resolution
- Serial RS 232 interface in the computer (COM1 .. COM8)
- Printer installed on LPT1 or via the network. All printers accepted by the Windows operating system can be used. A default printer must be set
- Connection cable between computer and scale
- Accessories (liquid container, cannula, oil).

### 2.2 Software installation

INFUSCALE is delivered as a packed file (zip). It contains the installation file as an exe file and the user manual as a pdf file.

To install INFUSCALE, double-click on the installation file 'Infuscale811E.exe'. After that an installation routine transfers all program, data and help files to the computer.

The installation routine creates a shortcut icon on the desktop. Double-clicking on it starts the INFUSCALE software.

**Note:** INFUSCALE uses an area in the Windows Registry as a cache during operation. Therefore, it is necessary to assign read and write permissions for the "Infuscale" key in the Windows Registry to the INFUSCALE user account.

**Note:** A printer must be set as the default printer on the computer used.

## 2.3 Supported scales

The following table shows some scale types supported by INFUSCALE. A comprehensive list can be found on the Internet at [www.infuscale.de](http://www.infuscale.de).

**Table 1: Selection of supported scales**

Manufacturer	Type series	Preset
Mettler	AE, AB-S, AG, AM, AT, AX, ML, MS, MT, MX, PB-S, PG-S, PM, PR, SB, SG, SR, UMT, UMX, XP, XS	2400 Bd, 7E1
Sartorius	AC, BA, BL, BP, CP, CPA, Cubis, ED, LA, LC, LP, MC, RC, SC, TE	9600 Bd, 7E1
Ohaus	GA, GT, Adventurer Pro, Discovery, Explorer	4800 Bd, 7E1
Chyo	MJ, MP, MK series	4800 Bd, 8N1
Precisa	300S, 360EP, 360ES, 321LT, 321LX, 321LS, 320XB, 165BJ	9600 Bd, 7E1
Core	Analytical balances ABJ-NM/ABS-N	9600 Bd, 7E1

Other scales with RS232 interface can also communicate with a PC or can be adapted (see 'custom auto' mode).

Column 3 of the table contains the interface parameters preset by the balance manufacturer. For Sartorius scales, for example, a baud rate of 9600 Bd, a data word length of 7 bits, an even parity E and 1 stop bit are preset. These values are automatically taken over from an internal table in the "Setup" screen by clicking on



However, other parameters can also be selected. It is important that the values set on the scale match those in the computer.

## 2.4 Adaptation to unsupported scales

By selecting "Custom" in the directory of supported scales (see Figure 3), other scales not yet supported can be adapted to INFUSCALE. The settings required here are described below.

### 2.4.1 Auto mode

In AUTO or CONTINUOUS mode, the scale continuously sends data to the computer via the interface. To operate the scale in this mode, the scale must be configured in the automatic (continuous) print mode and the "auto" selection must be marked in the INFUSCALE software in the "Setup", "Options" screen.

## 2.4.2 Request mode

In request mode, the scale transmits a value to the computer only if the computer has previously sent a request signal to the scale. To operate the scale in the request mode, the scale must be configured in the single print mode and the "requ" selection must be marked in the INFUSCALE software in the "Setup" , "Options" screen.

Also, the request code must be entered in the "Req" field.

For non-printable characters (control characters), the ASCII code is preceded by a "#".

**Table 2: Control character input**

Characters	ASCII code	Input in field "Req"
ESC	[27]	#27
CR	[13]	#13
LF	[10]	#10

For printable characters (e.g. letters and numbers), the ASCII code is preceded by an apostrophe (').

**Table 3: Input of printable characters**

Characters	ASCII code	Input in field "Req"
1	[49]	'1
P	[80]	'P

Example: The request code for Sartorius scales is e.g. the character string #27'P#13#10.

## 2.4.3 Setting the data format

The data format is set in the "Setup" screen in the "Options" frame in the "Par" section. The 4 fields define the data format of the set scale.

- Field 1: Number of the scale type
- Field 2: Scale index
- Field 3: First read character of a received data line from the left
- Field 4: Number of characters read from a data line

If the "Custom" scale type is selected in the scale list, you can enter your own values in fields 3 and 4.

Note: For Sartorius scales, the data format must be set to 16 digits.

## 2.5 Connection of scale and computer

The scale is connected to the RS232 interface (COM1 .. COM8) of the computer with the connection cable.

The RS 232 interfaces of the PC are configured as DTE (Data Terminal Equipment) with plug connection, those of scales as DCE (Data Communication Equipment) with socket connection. The connection consists at least of the send line, the receive line and the ground line. Additional handshake lines can be added.

**Table 4: Connection scheme**

Scale $\perp$	connected with	Pin 5 of the 9 pin connector	Mass
Scale-data out	connected with	Pin 2 of the 9 pin connector	Data from the scale to the PC
Scale-data in	connected with	Pin 3 of the 9 pin connector	Data from PC to scale

Electronic scales can be operated in two different modes together with INFUSCALE.

- Continuous data transmission to the computer (auto)
- Data transmission after request by the computer (requ, handshake mode)

We recommend to work in AUTO or CONTINUOUS mode at least in the beginning without handshake.

If the pin assignment is unknown, a function test should first be carried out by provisionally connecting the wires between the scale and the PC. It may happen that data lines 2 and 3 are not connected correctly at first attempt and have to be swapped.

On the scale side, the handshake must be set to OFF and the output mode to CONTINUOUS DATA OUTPUT (CONT or AUTO).

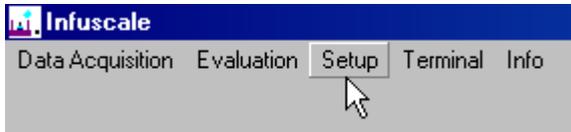
The settings: Baud rate, parity, data bits and stop bits must match on the scale and PC. For this purpose, read chapter 3 and match the settings on the PC with those on the scale.

The correct data transfer from scale to PC can be checked with the terminal function (see 3.1).

### 3 MAIN MENU AND SETUP

After starting INFUSCALE, the initial screen with the main menu appears.

Figure 2: Main menu

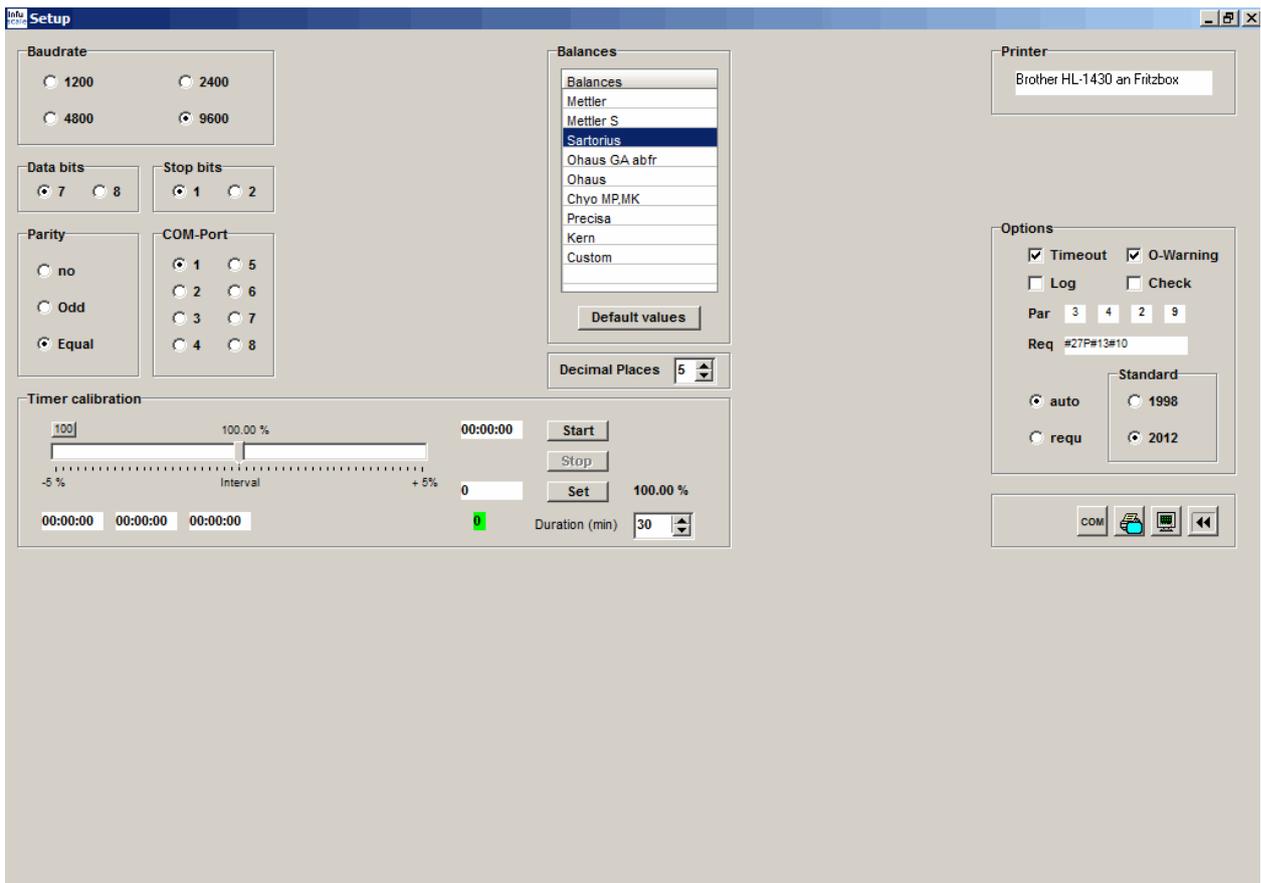


From here, the menu items "Data Acquisition", "Evaluation", "Setup", "Terminal" and "Info" are selected.

Now please click on "Setup".

In this menu item INFUSCALE is configured. At the very first call INFUSCALE searches for a free serial interface. After that the screen "Setup" appears.

Figure 3: Setup screen



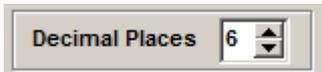
In this screen, the first thing to do is to select the connected scale. This is done by clicking on the corresponding name in the "Balances" window.

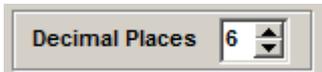
By clicking on



the interface parameters "Baudrate", "Data bits", "Stop bits" and "Parity" are taken automatically from Table 1: Selection of supported scales. COM port designates the scale interface.

The  key is used to hide ports that are not available.



In the field  operation of INFUSCALE with scales of up to 6 decimal places (resolution 1 µg) can be set. Default setting is 5.

### 3.1 Terminal function

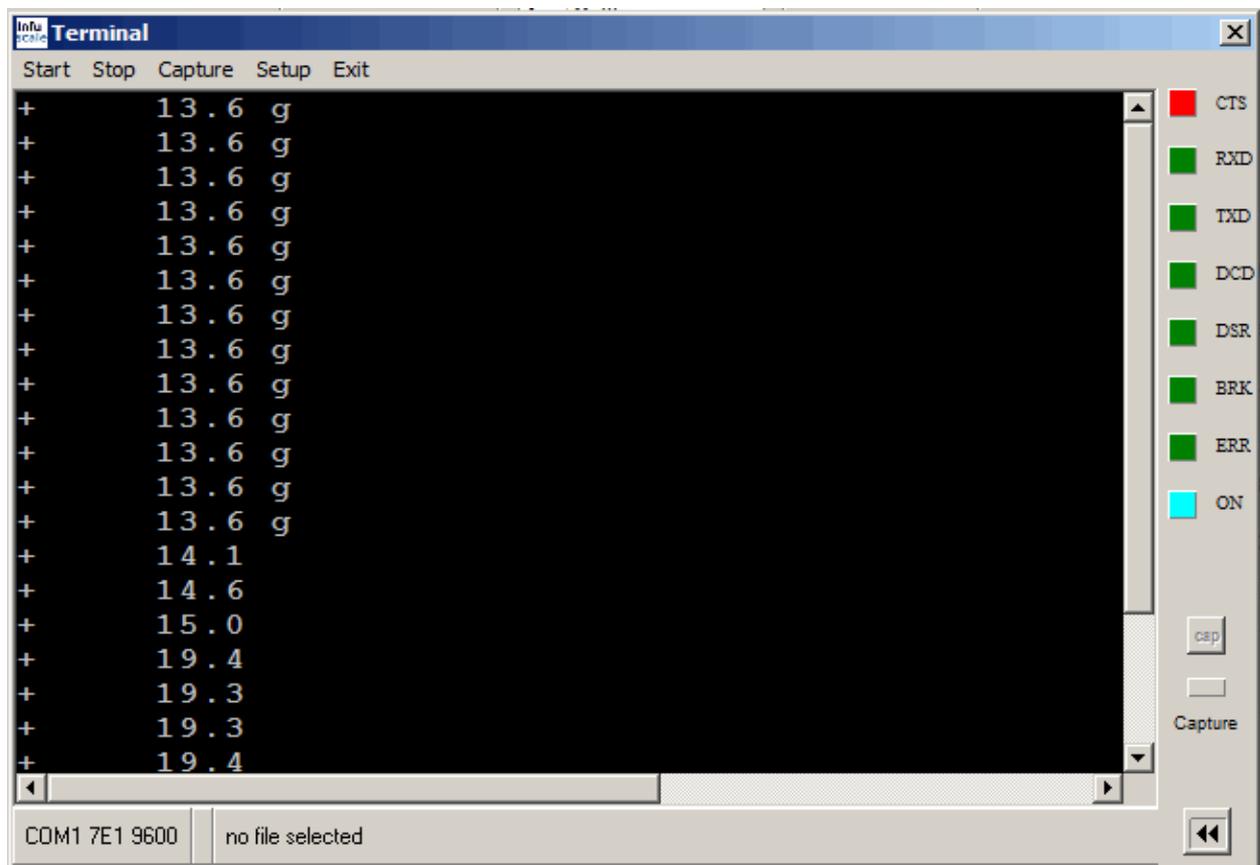
By clicking on "Terminal" in the main menu (Figure 2) or



in the "Setup" screen ( Figure 3), the terminal program opens.

It is used to control the scale interface and to record raw scale data as a capture file (extension "CAP") in "auto" mode.

Figure 4: Terminal screen with weighing data



The following functions are implemented:

Menu item	Function
Start	Start displaying the data transmitted by the scale (auto)
Stop	Display stop
Capture	Entering the file name of the capture file
Setup	Input of the interface parameters
Exit	Switching off the terminal

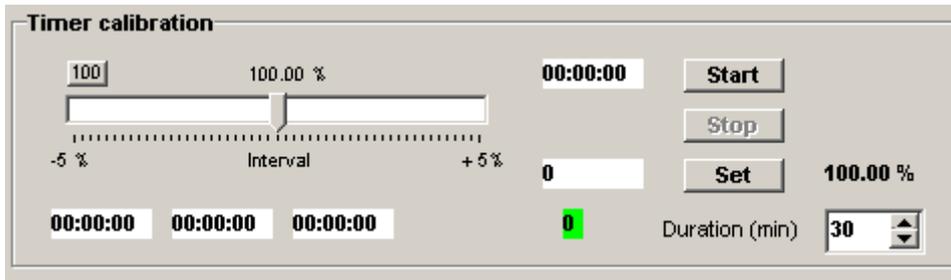
Clicking on the  key starts the recording of the scale data (capture function). When the capture function is activated, a yellow lamp lights up. A further click ends the recording.

The seven green square light fields at the upper right edge indicate the state of the interface. Red indicates an active level. When the terminal is switched on, the blue light field to the left of "ON" is illuminated.

### 3.2 Timer calibration

The internal timer controls the acquisition of the scale data very precisely. Its setting does not normally need to be changed. However, it is possible to speed it up or slow it down by a maximum of 5% compared to the internal PC clock.

Figure 5: Timer calibration field



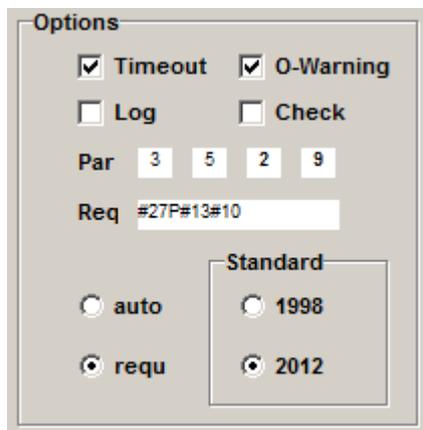
A changed value can be set with the slider. After clicking on "Set", this value is adopted by the system. Click on  set the timer to 100 %.

It is also possible to perform an automatic calibration run. The duration of this process can be defined by setting the minutes in the field to the right of "Duration (min)". After clicking on "Start", the test begins. The green field then shows the difference between the PC time and the timer time in seconds. The percentage deviation can be seen in the field above. After the set test duration has elapsed or after clicking on "Stop", the optimized timer value is displayed in the field above the test duration. It is accepted by the system by clicking on "Set".

### 3.3 Options

The following selections are to be made in the "Options" frame:

Figure 6: Option settings



Timeout	If this field is checked, a message will be displayed if no data has been transmitted from the scale for at least 4 seconds.
U-Warning	If this field is marked, an overwrite warning will be issued at the beginning of a measuring process in the menu item DATA AQUISITION/MEASUREMENT after clicking the start button, if a file with the same name already exists.
Log	If this field is checked, a log file will be created in addition to the INFUSCALE file during data acquisition. This file logs the data acquisition process. It has the extension "LOG".
Check	If this field is marked, a horizontal scroll bar appears in the "Scales" field. By moving the cursors to the right, all other fields of the table can be made visible. They contain the preset interface parameters of the individual scale types.
Par	The 4 fields refer to the data format of the set scale. Field 1: Number of the scale type Field 2: Scale index Field 3: First read character of a data line from the left Field 4: Number of characters read from a data line If the scale type "Custom" is selected in the scale list, you can enter your own values in fields 3 and 4. This allows scales not yet supported to be adapted to INFUSCALE.
Req	Entering the request code for "Custom" scales
auto	Operating mode <u>auto</u> means that the scale continuously sends data to the computer via the interface.
requ	Operating mode <u>requ</u> means that the scale transmits a value only on request by the computer. With some scales, both operating modes (auto or requ) can be selected.
Standard	Here you can set the standard according to which INFUSCALE performs the evaluation. 1998 = 1st edition , 2012 = 2nd edition.

The key  leads back to the main menu.

## 4 CLASSIFICATION OF INFUSION PUMPS

### 4.1 Volumetric infusion controllers, infusion pumps and syringe pumps

The standard prescribes the following measurement conditions:

**Table 5: Measuring conditions 4.1**

<b>Measuring interval S:</b>	Not specified in IEC60601-2-24:2012. In EN60601-2-24:1998 is S=30 sec
<b>Set delivery rate Qi:</b>	The measurement must be carried out at the following delivery rates: a) For volumetric pumps and infusion controllers: - smallest adjustable rate, but at least 1 mL/h - intermediate rate: 25 mL/h b) For syringe pumps: - smallest adjustable rate, but at least 1 mL/h - intermediate rate: 5 mL/h
<b>Measurement duration:</b>	At least two hours

Further details can be found in the infusion standard and Table 7 or Table 8. The evaluation with INFUSCALE is described in section 6.3.2 of this user manual.

### 4.2 Drip-regulated infusion controllers and infusion pumps

The standard does not recommend the gravimetric measuring method for these devices, but a drop counting method.

### 4.3 Infusion pumps for ambulatory use type 1

These are ambulatory pumps with continuous delivery characteristics in accordance with Section 201.12.1.103 or 50.104 of the standard. This prescribes the following measurement conditions:

**Table 6: Measuring conditions 4.3**

<b>Measuring interval S:</b>	S = 900 s = 15 min
<b>Delivery rate Qi:</b>	The measurement must be carried out at the following delivery rates: - at the smallest adjustable rate - at the intermediate rate specified as typical by the manufacturer

Further information can be found in the infusion standard and Table 7 or Table 8. The evaluation with INFUSCALE is described in section 6.3.4 of this user manual.

#### **4.4 Infusion pumps for ambulatory use type 2**

These are pumps with quasi-continuous delivery, i.e. repetitive delivery of the same boli over the entire delivery period. The measurement is to be carried out with 20 and then with further 100 boluses at the intermediate delivery rate recommended by the manufacturer.

For more details on the procedure, refer to the infusion standard and Table 7 or Table 8. The evaluation with INFUSCALE is described in section 6.3.5 of this user manual.

#### **4.5 Infusion pumps for ambulatory use type 3**

These are ambulatory infusion and syringe pumps with bolus facilities (pumps that can deliver single discrete boluses).

The measurement is to be carried out with 25 consecutive boluses at the lowest delivery rate either by hand or program-controlled. For more details on the procedure, refer to the infusion standard and Table 7 or Table 8. The evaluation with INFUSCALE is described in section 6.4.1 of this user manual.

#### **4.6 Infusion pumps for ambulatory use type 4**

Combination of quasi-continuous delivery and bolus delivery. The tests are performed according to the infusion standard and Table 7 or Table 8.

#### **4.7 Infusion pumps for ambulatory use type 5**

Only for parenteral nutrition or patient-controlled infusion. For details on the procedure, refer to the infusion standard and Table 7 or Table 8.

Note: The testing of nutrition pumps must be carried out with the nutrition liquid provided by the manufacturer. Before starting the measurement, the density of the nutrition fluid must be determined and entered in the field provided.

#### **4.8 Other pumps for medical applications**

The standard does not contain regulations for implantable pumps and other pump systems for medical applications.

However, INFUSCALE can also be used with these pumps.

## 4.9 Overview of infusion pumps

**Table 7: Delivery rates and bolus volumes according to EN60601-2-24:1998**

Type	Min. Rate (>=1ml/h)	Interm. Rate	Interm. Rate +100 mmHg	Interm. Rate -100 mmHg	Interm. Rate, Container 0,5m lower	Bolus Min.	Bolus Max.	Sample intervall	Test acc. to section	Infuscale-button
Vol. Contr	x	25mL/h		x				30 s	50.102	102
Vol. Pump	x	25mL/h	x	x	x	x	x	30 s	50.102 (50.106)	102 (106)
Syr. Pump	x	5mL/h	x	x		x	x	30 s	50.102 (50.106)	102 (106)
Drop contr.	x	20/min		x				1 min	50.103	-
Drop pump	x	20/min	x	x				1 min	50.103	-
Amb. Type1	x	typical						15 min	50.104	104
Amb. Type 2		typical							50.105	105
Amb. Type 3						x	x		50.106	106
Amb. Type 4	x	typical				x	x		50.107	104-106
Amb. Type 5	x	typical				x	x		50.108	102-106

**Table 8: Delivery rates and bolus volumes according to IEC60601-2-24:2012**

Type	Min. Rate (>=1ml/h)	Interm. Rate	Interm. Rate +100 mmHg	Interm. Rate -100 mmHg	Interm. Rate, Con- tainer 0,5m lower	Bolus Min.	Bolus Max.	Sample intervall	Test acc. to section	In- fuscale- button
Vol. Contr	x	25mL/h		x					102	102
Vol. Pump	x	25mL/h	x	x	x	x	x		102 (105)	102 (105)
Syr. Pump	x	5mL/h	x	x		x	x		102 (105)	102 (105)
Amb. Type 1	x	typical						15 min	103	103
Amb. Type 2		typical							104	104
Amb. Type 3						x	x		105	105
Amb. Type 4	x	typical				x	x		106	103-105
Amb. Type 5	x	typical				x	x		107	102-105

#### 4.10 Classification according to application areas

The British Health Ministry has published recommendations for users of medical infusion pumps. These publications are based on technical evaluations, user assessments, incident reporting and on own evaluations. Device bulletin 2003(02) addresses problems in the use and selection of infusion systems and the training of users. It raises awareness of the nature of infusion systems, their advantages and risks.

Regarding area of clinical application, pumps have been divided into three major categories according to the potential infusion risks. These categories A, B, and C are shown in the next table with a list of the performance parameters critical to each. The categories have been selected on the principle that, in general, the greater the potential risks associated with therapies, the higher the performance needed and the more important are the safety features.

**Table 9: Therapy categories and performance parameters**

Therapy Category	Therapy description	Patient group	Performance data
A	Drugs with narrow therapeutic margin	Any	Good long-term accuracy
	Drugs with short half-life (< 5 min)	Any	Good short-term accuracy
	Any infusion given to neonates	Neonates	Rapid alarm after occlusion Small occlusion bolus Able to detect very small air embolus Small flow rate increments Good bolus accuracy Rapid start-up time
B	Drugs, other than those with a short half-life (> 5 min)	Any except neonates	Good long-term accuracy Alarm after occlusion
	TPN Fluid maintenance Transfusions	Volume sensitive except neonates	Small occlusion bolus Able to detect small air embolus Small flow rate increments
	Application of Diamorphin (long half life of metabolite)	Any except neonates	Bolus accuracy
C	TPN Fluid maintenance Transfusions	Any except volume sensitive or neonates	Long-term accuracy Alarm after occlusion Small occlusion bolus Able to detect air embolus Incremental flow rates

The minute-to-minute variability of flow becomes very important where drugs with short half-lives are being administered. The importance derives from the need to prevent undesirable fluctuation of effect-site concentration of the drug. There is documented evidence that minute-to-minute variability of flow can cause variation of physiological parameters and consequent difficulties in management, in both adults and neonates, where the half-life of the drug is short.

Short-term accuracy is expressed by the concept of **constancy index**. This is the shortest period during the pump's steady-state operation over which measurement of output consistently falls within  $\pm 10\%$  of the mean rate. The data are derived from the flow tests performed over 24 hours

at 1 mL/h. Flow is recorded at 30 second intervals over the final 18 hour period. And the average rate compared with flow over each short period.

The constancy index of the pump should be less than or equal to the half-life of the drug used. Syringe pumps have a shorter constancy index than volumetric pumps i.e. a low constancy index indicates good short-term flow rate accuracy.

## 5 CARRYING OUT THE MEASUREMENTS

### 5.1 Measurement setup

The measurement setup (Figure 1) consists of the following components:

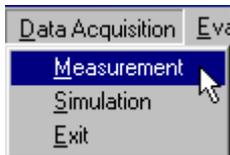
- Scale with RS232 interface
- Windows computer with RS232 interface COM1 to COM8
- Connection cable between computer and scale
- Liquid container
- Silicone oil for oil layer
- Cannula (G18 or G21)

The scale is set up and calibrated completely level and vibration-free. The reservoir of the infusion pump to be checked is filled with water (according to ISO class III). The infusion set connected and equipped with a long cannula is vented. A layer of oil (approx. 0.5 cm) floats above a small amount of water in the liquid container located on the weighing surface. This is intended to reduce the evaporation of the water during prolonged measurements.

The tip of the cannula is located directly under the oil layer so that there is an uninterrupted water column between the infusion container, the infusion line and the liquid container on the scale. This prevents the measurement accuracy from being influenced by the formation of drops at the end of the cannula.

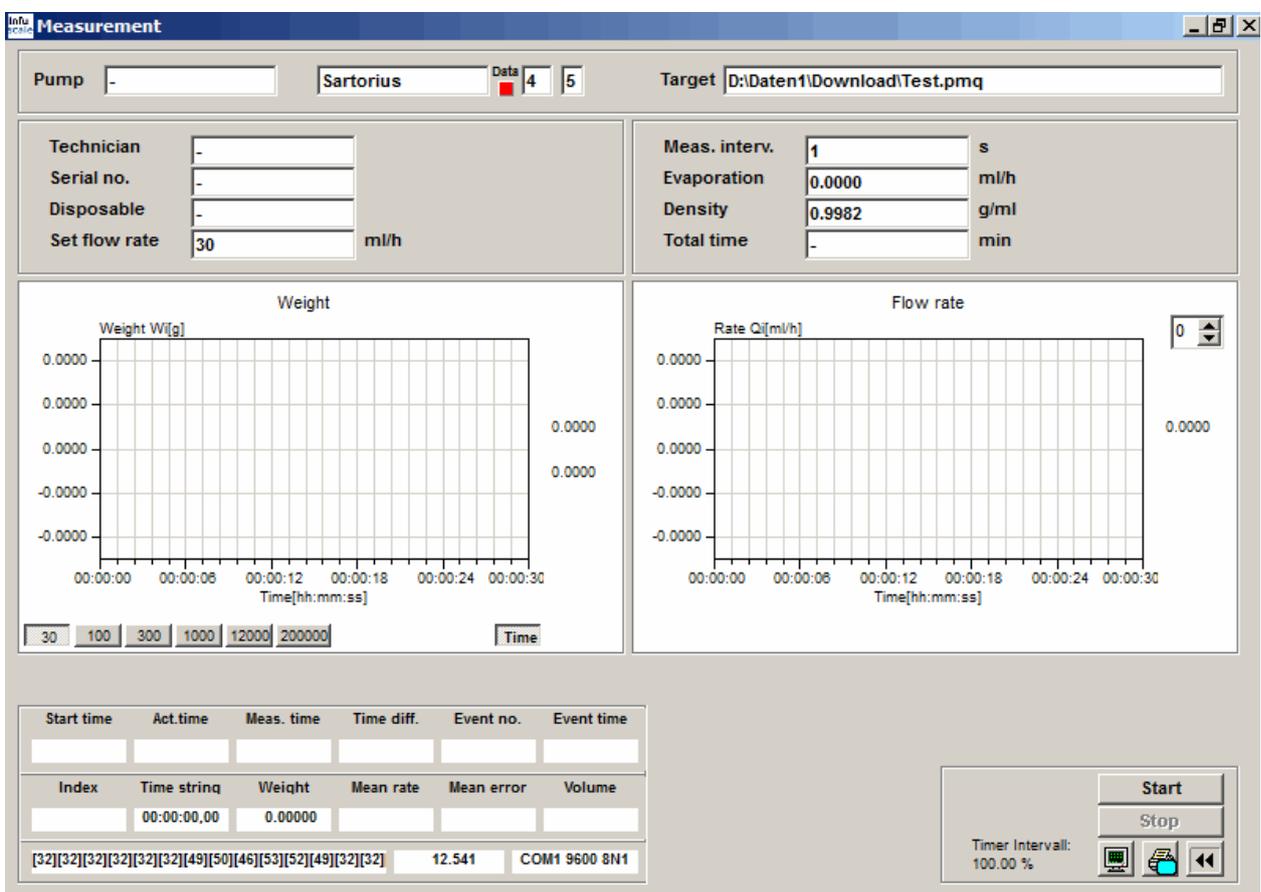
## 5.2 Measurement data acquisition

For measurement data acquisition, please click on "Data Acquisition" in the main menu and then on "Measurement".



The following screen appears:

Figure 7: Measurement data acquisition screen



### 5.2.1 Input fields

In the upper part of the screen are the input fields:

- Pump: Name of the infusion pump to be tested, next to it is the scale type.
- Target: Name of the destination file in which the weighing data is to be saved.
- Technician: Name of the technician performing the measurement
- Serial no.: Serial number of the infusion pump

- Disposable: Disposable used
- Set flow rate: Set delivery rate of the infusion pump
  
- Meas. interv.: Measuring interval in seconds
- Evaporation: Evaporation flow rate in mL/h
- Density: Density of the pumped liquid in g/mL
- Total time: Measuring duration limit in minutes (0 or - = measuring duration unlimited)

When entering the parameters please take into account the conditions, described in the IEC601-2-24 standard, and referenced in chapter 4 of this manual. With the TAB key or after pressing ENTER the input marker jumps to the next field.

The shortest measuring interval is 1 second. It should be noted that the measurement error (see chapter 7) increases with this short time.

In the center of the upper part of the screen, the scale marked in "Setup" is displayed.

To the right of this is a green display field (Data). It serves as a data indicator. Each time a new line of data arrives in the PC, the display briefly changes from "green" to "red".

The numbers to the right indicate the scale index and the number of maximum decimal places of the scale. They can be selected in the "Setup" menu item.

On the far right are the file name and path of the INFUSCALE file to be created. They can be changed after clicking the display field.

In the upper right corner of the "Flow rate" graph there is a field for manual setting of the Y-scale.

### 5.2.2 Control of data transmission

The display fields in the lower left part of the screen are used to check the measurement.

Figure 8: Values displayed during data acquisition

Start time	Act.time	Meas. time	Time diff.	Event no.	Event time
11:18:49	11:19:20	11:19:19	00:00:30		
Index	Time string	Weight	Mean rate	Mean error	Volume
30	00:00:30,00	20.00000	2404.32779	7914.43	20.03606
[32][32][32][32][32][32][32][50][48][46][49][56][32][32]				20.18	COM1 9600 7E1

At the very bottom, the data transmitted by the scale appear in ASCII coding. The character [32] represents the space, [48] the zero. To the right is the data line in normal readable form. In "auto" mode, it is easy to check whether the data arrive correctly at the PC by observing these two fields. The set port parameters are shown at the bottom right.

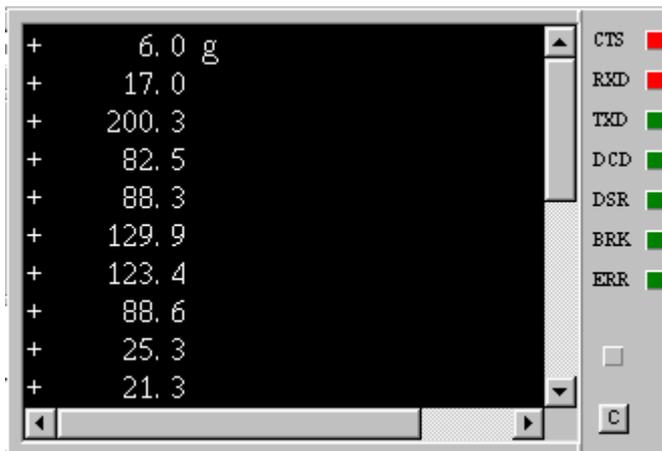
### 5.2.3 Terminal function

By clicking on



the terminal program screen appears. It enables the control of the incoming scale data and RS232 control signals. In the "requ" mode, the control commands sent from the PC to the scale are also displayed.

**Figure 9: Terminal display during measurement**



By clicking on  the raw scale data are recorded as a capture file (extension "CAP"). When this function is activated, a yellow lamp lights up. Another click switches the raw data recording off again.

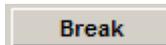
The seven square light fields on the right edge indicate the state of the RS-232 interface. Red means an active level.

### 5.2.4 Start measurement

Once all parameters have been entered, data acquisition can be started by clicking on



Instead of the Start key, the key



...appears.

A click on this button interrupts the data acquisition. Another click resumes it.

One click on the



button stops data acquisition and saves the data to disk.

The resulting file contains, in addition to the entered data, the time and the corresponding measured weight per line. Each event marked by pressing the space bar is saved in a separate line. The name of the technician performing the measurement is saved as the last line.

Example:

**Figure 10: Extract from an INFUSCALE file**

```

TIME INTERVAL (SEC) :    30
SET FLOW RATE (ML/H) :  20.0000
EVAPORATION   (ML/H) :    0.0000
DENSITY       (G/ML) :    0.9982
NAME OF PUMP   : Example 5
SERIAL NUMBER  : -
DISPOSABLE     : -
13:26:33,25   0.00000
13:27:03,30   0.02041
13:27:33,29   0.12840
13:28:03,28   0.28762
13:28:33,27   0.45998
13:29:03,26   0.64032
13:29:33,25   0.80385
13:30:03,29   0.96463
13:30:33,28   1.12811
13:31:03,27   1.29109
13:31:33,26   1.44685
13:32:03,25   1.59950
13:32:33,29   1.74942
13:33:03,28   1.90455
13:33:33,27   2.06292
13:34:03,26   2.23061
etc.
    
```

During the program run, the following values are continuously displayed in the lower left display field (see Figure 8: Values displayed during data acquisition Figure 11)

Top row:

1. Start time
2. Current PC time
3. Measuring time
4. Time difference between measuring time and start time
5. Event number
6. Event time

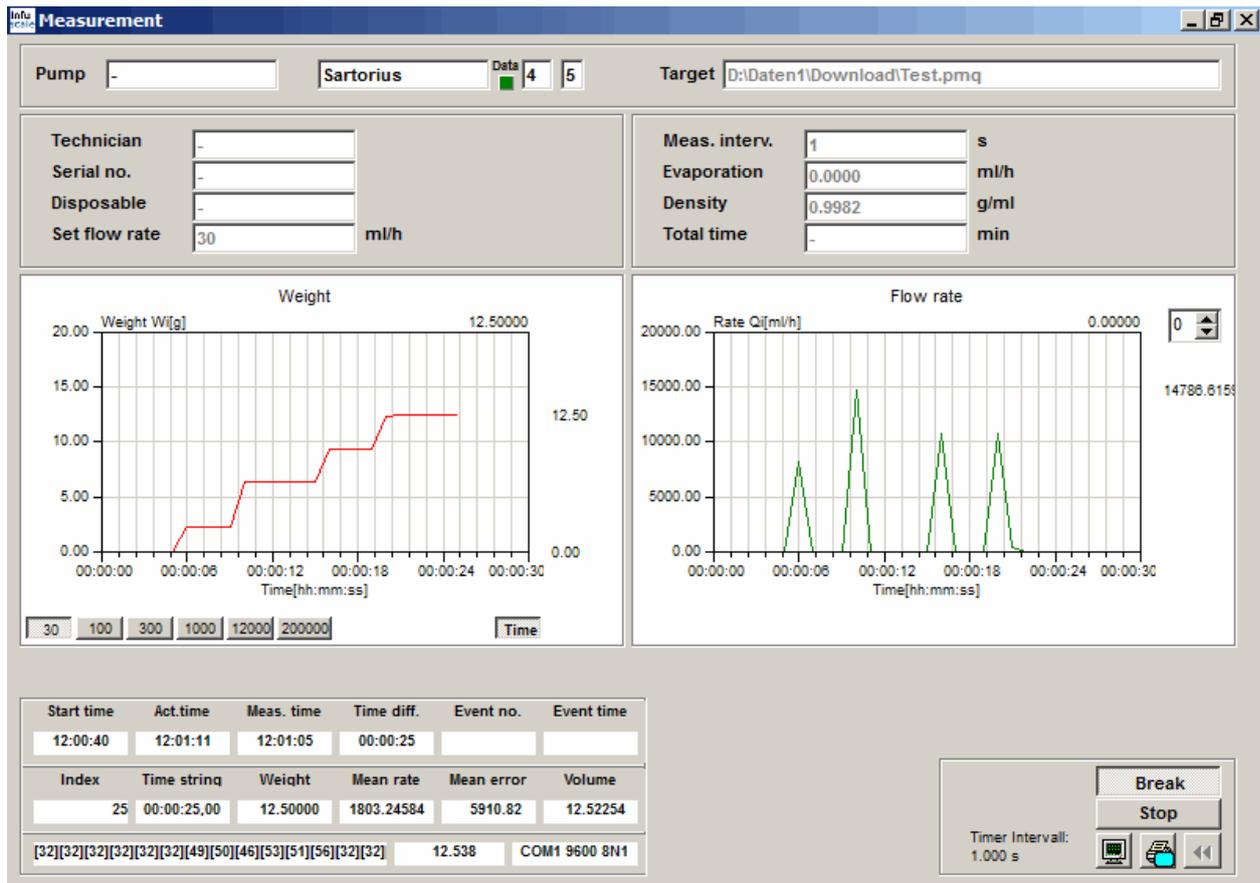
Middle row:

1. Index number
2. Stored time string
3. Stored weight in grams
4. Averaged flow rate since start of measurement in mL/h (mean rate)
5. Percentage deviation of the averaged flow rate from the target flow rate
6. Current delivered volume in mL

In the two middle windows, the weight and the current flow rate are displayed as graphs and continuously updated. The key fields at the bottom left enable the setting of feed rate and resolution. If, for example, the 30 key is activated, as in the picture below, a total of 30 measuring points are displayed. If this number is exceeded, the curve scrolls to the left. Clicking on 200000 means the display of the maximum possible number of 200000 measuring points.

If the **Time** key is pressed, the display of the minutes on the X axis changes to the time format hh:mm:ss. 1 minute is then displayed as 00:01:00.

Figure 11: Screen during data acquisition



### 5.2.5 Event marker

An event marker can be set during the measurement. This is done by pressing the SPACEBAR on the PC keyboard. Such an event is displayed in the graphs and the control panel and saved with the INFUSCALE file. Each event line starts with a "Z".

Example for event number 1: Z 1 56:01:25,00

A saved event is also displayed in the evaluation graphs and the table.

### 5.2.6 Storage of Graphics on file and to Clipboard

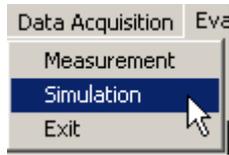
If the cursor is located on one of the two graphs, the following menu can be displayed by clicking the right mouse button:



The left mouse button is now used to save the respective graphic as a file in bitmap or JPG format. With "CopyToClipboard" the graphic can be saved to the clipboard, which makes it easy to paste it into a text program.

### 5.3 Simulation

The simulation of a measurement data acquisition can be started by clicking on "Simulation" in the menu item "Data Acquisition".



Here, instead of a scale, an existing INFUSCALE file or a raw data file (Exit-file) is used as the data source. It is set by clicking on the "Source" window at the top left of the screen. Further operation is as described in 5.2.

By marking the field  x10  x100 the simulation is accelerated by a factor of 10 or 100 respectively.

## 6 EVALUATION OF THE MEASUREMENT DATA

### 6.1 Preliminary remarks on the standard

In Edition 2.0 of IEC60601-2-24:2012, the numbering of the chapters has been changed compared to the 1998 version. The following table contains a comparison of the chapter numbers referred to in INFUSCALE.

**Table 10: Comparison of chapter numbers**

Edition 1.0 (1998)		Edition 2.0 (2012)		
1998		2012		Setting of Standard (see 3.3)
Chapter	Infuscale button	Chapter	Infuscale button	Chapter heading
50.101		201.12.1.101		General formula
50.102	102	201.12.1.102	102	Accuracy tests for Volumetric Infusion Controllers, Volumetric Infusion Pumps and Syringe or Container Pumps
50.103	103	not applicable	-	
50.104	104	201.12.1.103	103	Accuracy tests for Infusion Pump for Ambulatory Use type 1
50.105	105	201.12.1.104	104	Accuracy tests for Infusion Pump for Ambulatory Use type 2
50.106	106	201.12.1.105	105	Accuracy tests for Infusion Pump type 3
50.107	104-106	201.12.1.106	103-105	Accuracy tests for Infusion Pump type 4
50.108	102-106	201.12.1.107	102-105	Accuracy tests for Infusion Pump type 5

In the 1998 version of the standard, a fixed value of 30 seconds was prescribed for the measurement interval *S* in Chapter 50.102 (volumetric infusion controllers, volumetric infusion pumps and syringe pumps). In contrast, the 2012 version of the standard now allows any value for *S*. In practical terms, however, this does not play a major role, since the fixed observation windows of 2, 5, 11, 19 and 31 minutes in conjunction with the calculation formulas are based on a measurement interval of 30 seconds and therefore only this value for *S* is reasonable.

It is possible to switch between the first (1998) and the second (2012) edition of the standard in the setup menu.



This adapts the key designations and the conditions for evaluating the INFUSCALE files to the selected standard. 1998 means 1<sup>st</sup> edition, 2012 means 2<sup>nd</sup> edition.

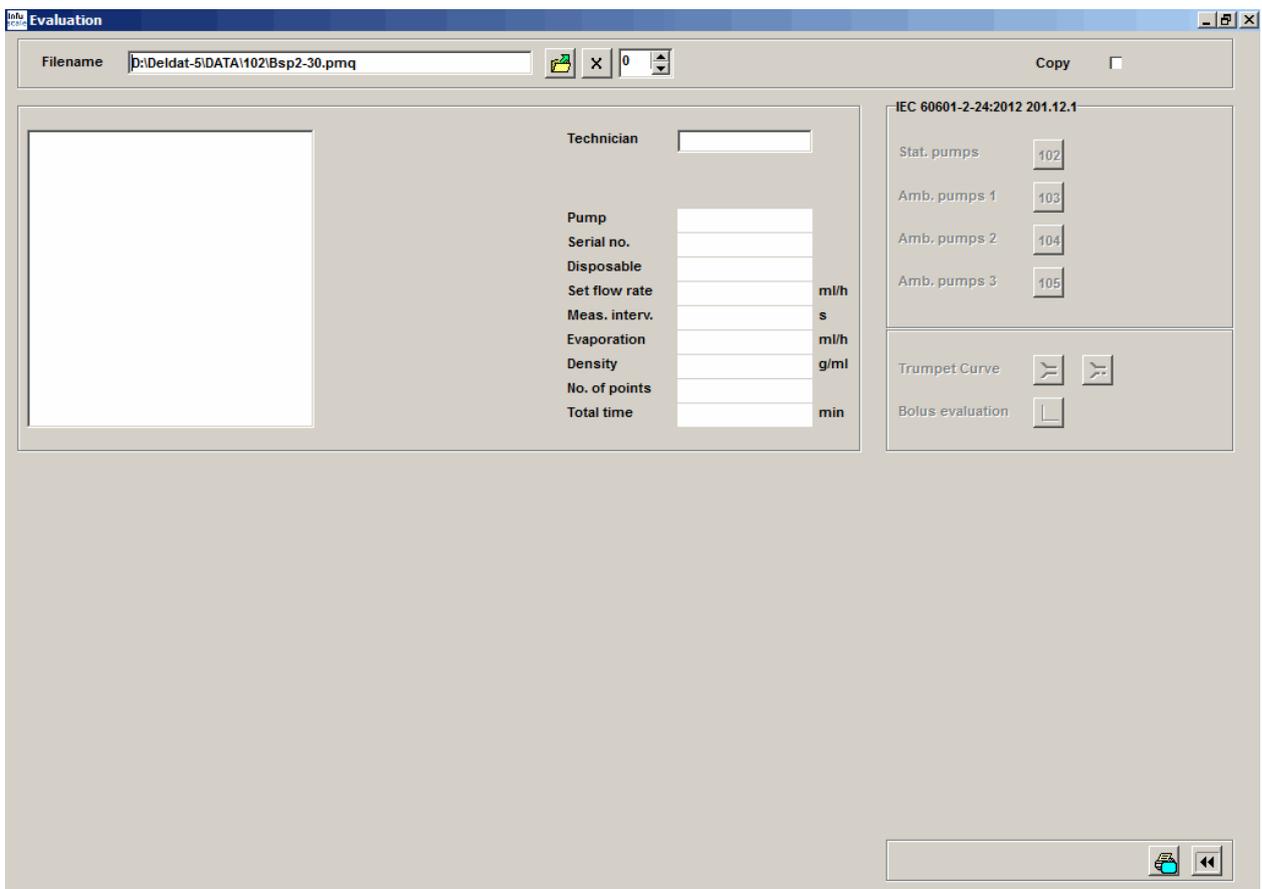
## 6.2 Loading the INFUSCALE file

To evaluate the measured data, please go to the main menu and click on "Evaluation".



The following screen appears:

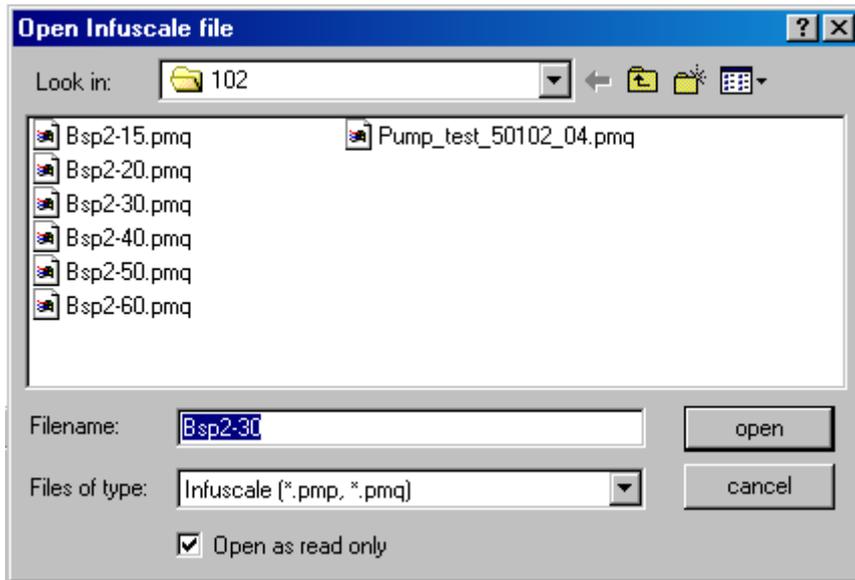
Figure 12: Initial "Evaluation" screen



At the present time, the buttons in the frame "IEC60601-2-24,201.12.1" on the right side of the screen are deactivated. Only when the displayed INFUSCALE file has been loaded by clicking on the  button, they become active, but only those whose function is meaningful according to the standard. With them one can select the further evaluation steps later.

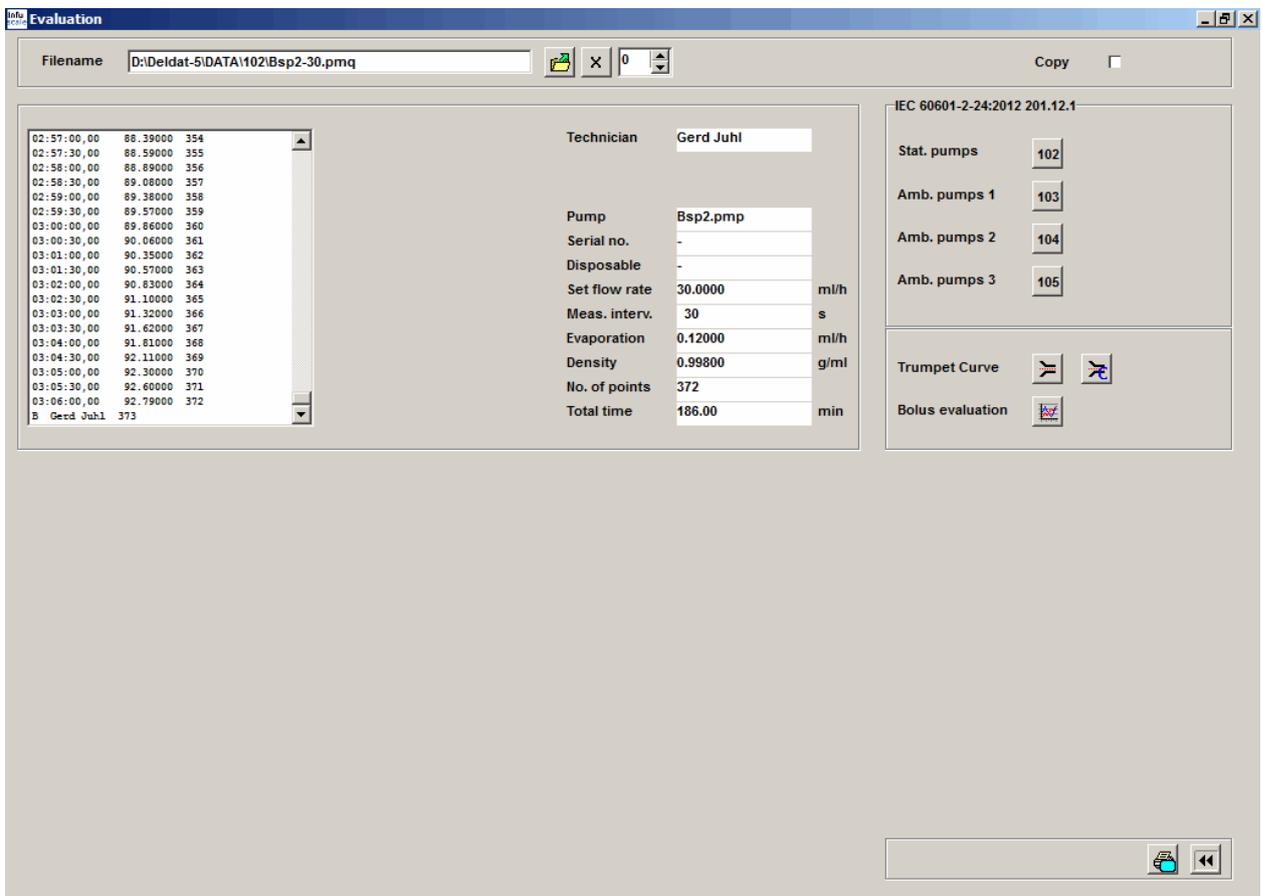
If a file other than the one displayed is to be loaded, this can be done by clicking on the field next to "File name". A selection window then opens in which the desired file is marked and opened.

Figure 13: Open file



After clicking the  button, the displayed file is loaded.

Figure 14: File was loaded



A click on  cancels the loading process.

After loading, the raw data and the line index appear in the left window. In the fields to the right of this, the saved file parameters (Pump, Serial no., etc.) are displayed.

If desired, the name of the technician performing the measurement can be entered.

The keys   and  take the user directly to the "Trumpet curve" , "Modified trumpet curve and constancy index" or "Bolus evaluation" program modules. The calculations are performed without any restrictions regarding the minimum duration (> 2 hours).

Click on  to return to the main menu.

## 6.3 The trumpet curve

### 6.3.1 Meaning of the trumpet curve

A trumpet curve according to EN60601-2-24:1998 and IEC60601-2-24:20120 is the graphical representation of the maximum and minimum deviations of the measured flow rate averaged in 5 or 6 different observation intervals compared to the set target flow rate of the pump under test. From it, the averaged flow rate deviations per time interval can be obtained.

In the physician's practical use of an infusion pump, the trumpet curve is useful information in deciding whether the pump can be used with the intended drug.

Pharmaceuticals with short elimination half-lives in particular place high demands on the delivery consistency. For a drug whose plasma elimination half-life is one minute, for example, flow rate fluctuations of 15% per minute cause similar fluctuations in plasma levels. A predictable, constant drug effect cannot be achieved in this case.

#### Example:

Intravenously administered insulin has an elimination half-life of 15 minutes. Flow rate fluctuations of  $\pm 15\%$  on average in a time interval of 40 minutes cause comparable fluctuations in plasma levels and thus in the effect.

### 6.3.2 Trumpet curve for volumetric pumps and controllers

Edition 1.0 (1998)		Edition 2.0 (2012)	
Chapter	Key	Chapter	Key
50.102	<b>102</b>	201.12.1.102	<b>102</b>

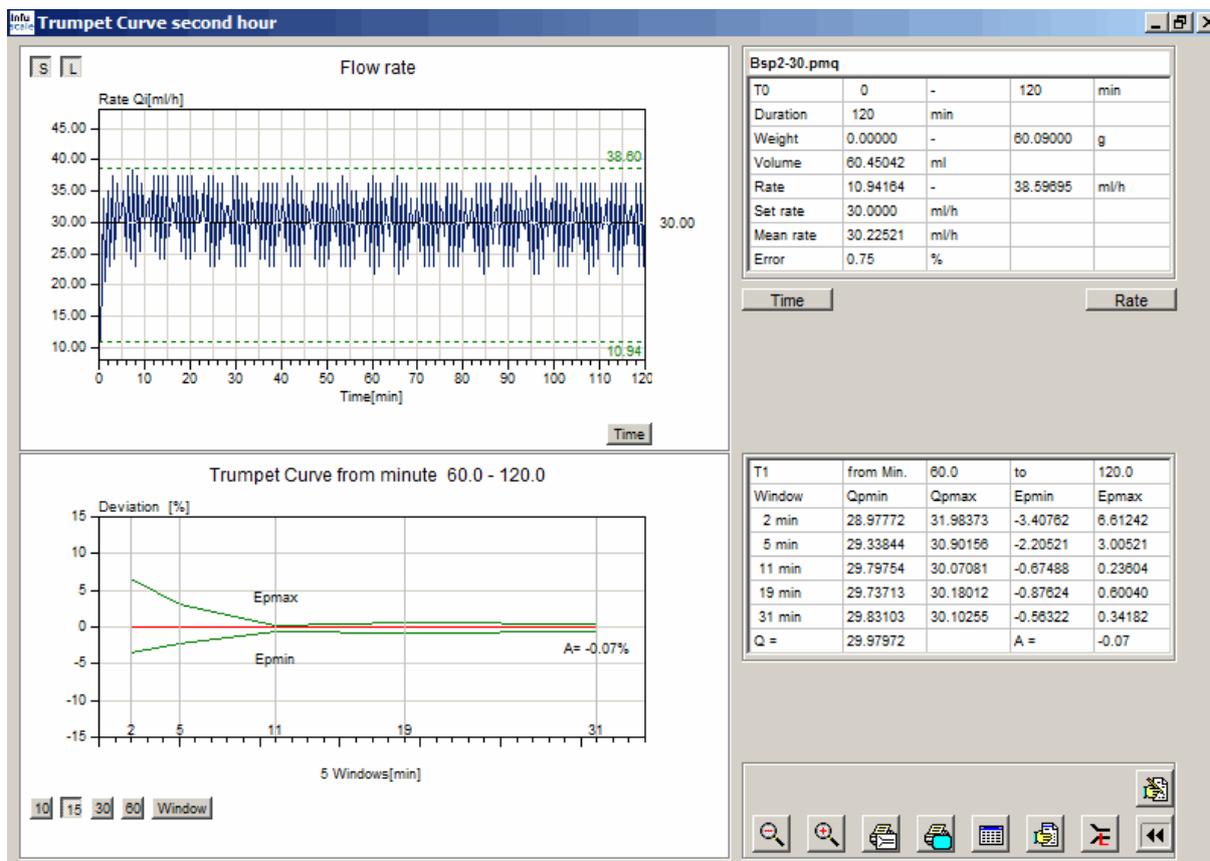
The **102** key is activated if volumetric infusion controllers, infusion pumps and syringe pumps are to be evaluated (see Chapter 4.1). The data acquisition time must be longer than 2 hours. After clicking this key, the program evaluates the data according to section 50.102 or 201.12.1.102 of the standard. Accordingly, the observation intervals 2, 5, 11, 19 and 31 minutes are used and in the second hour as well as in the last hour

- the minimum flow rate  $Q_{pmin}$
- the maximum flow rate  $Q_{pmax}$
- the largest negative deviation of the mean flow rate  $E_{pmin}$
- the largest positive deviation of the mean flow rate  $E_{pmax}$
- the total percentage error A in relation to the set delivery rate.

These results are displayed as a "trumpet curve".

The next figure shows the evaluation of the second hour of the example file BSP2-30.pmq.

Figure 15: Trumpet curve 2nd hour



The two fields on the right side of the screen contain the calculated data as numbers, such as the minimum - or maximum flow rates (here 10.94164 or 38.59695 mL/h). The value of the total error A is to the right of the trumpet curve (here A = - 0.07 %).

Note the row of keys at the bottom left: **10** **15** **30** **60** **Window**

These keys can be used to set the Y-axis scaling of the trumpet curve. The default setting is  $\pm 15\%$  deviation.

The **S** key at the top left of the screen can be used to change the scaling of the Y-axis. If this key is not pressed, the Y-range of the curve corresponds to the specifications of the standard:  $Y_{max} = 2 * \text{set flow rate}$ ,  $Y_{min} = -0.2 * \text{set flow rate}$ .

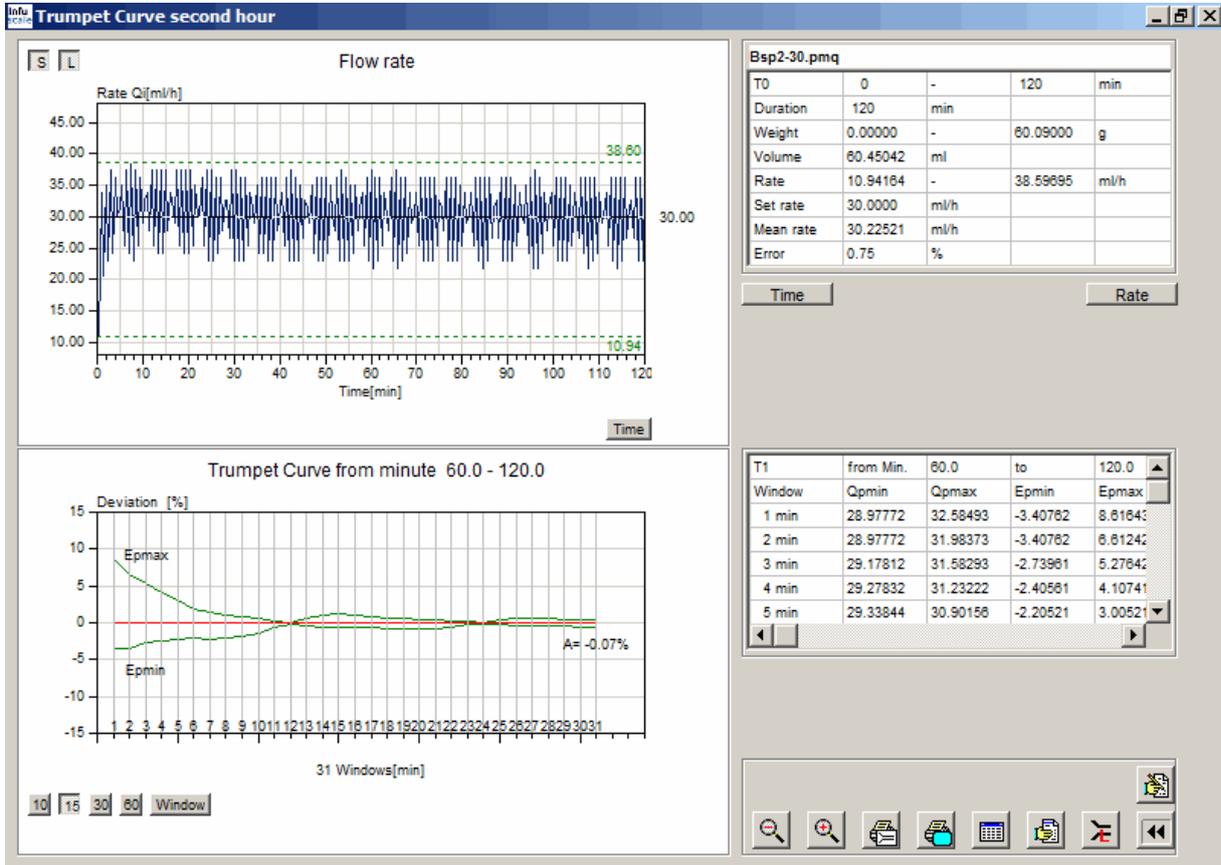
If **S** pressed, the curve is inserted into the Y-scale as well as possible.

Clicking the **Time** button calculates and displays the trumpet curve for the last hour, as required by Section 201.12.1.102 of the standard.

### 6.3.3 Representation according to ANSI/AAMI 2009

A click on the button **Window** creates a trumpet curve with 31 observation windows according to the ANSI/AAMI standard of 2009 as shown in Figure 16 below. Clicking again restores the original trumpet curve according to IEC60601-2-24 with 5 windows.

Figure 16: Trumpet curve 2nd hour with 31 observation windows



### 6.3.4 Evaluation of infusion pumps for ambulatory use type 1

Edition 1.0 (1998)		Edition 2.0 (2012)	
Chapter	Key	Chapter	Key
50.104	<b>104</b>	201.12.1.103	<b>103</b>

The **104** or **103** key is activated if infusion pumps for ambulatory use of type 1 are to be evaluated (see Chapter 4.3). The measuring interval here is 15 minutes. The specifications in section 50.104 or 201.12.1.103 of the standard apply.

After clicking the button, an input line opens at the bottom.

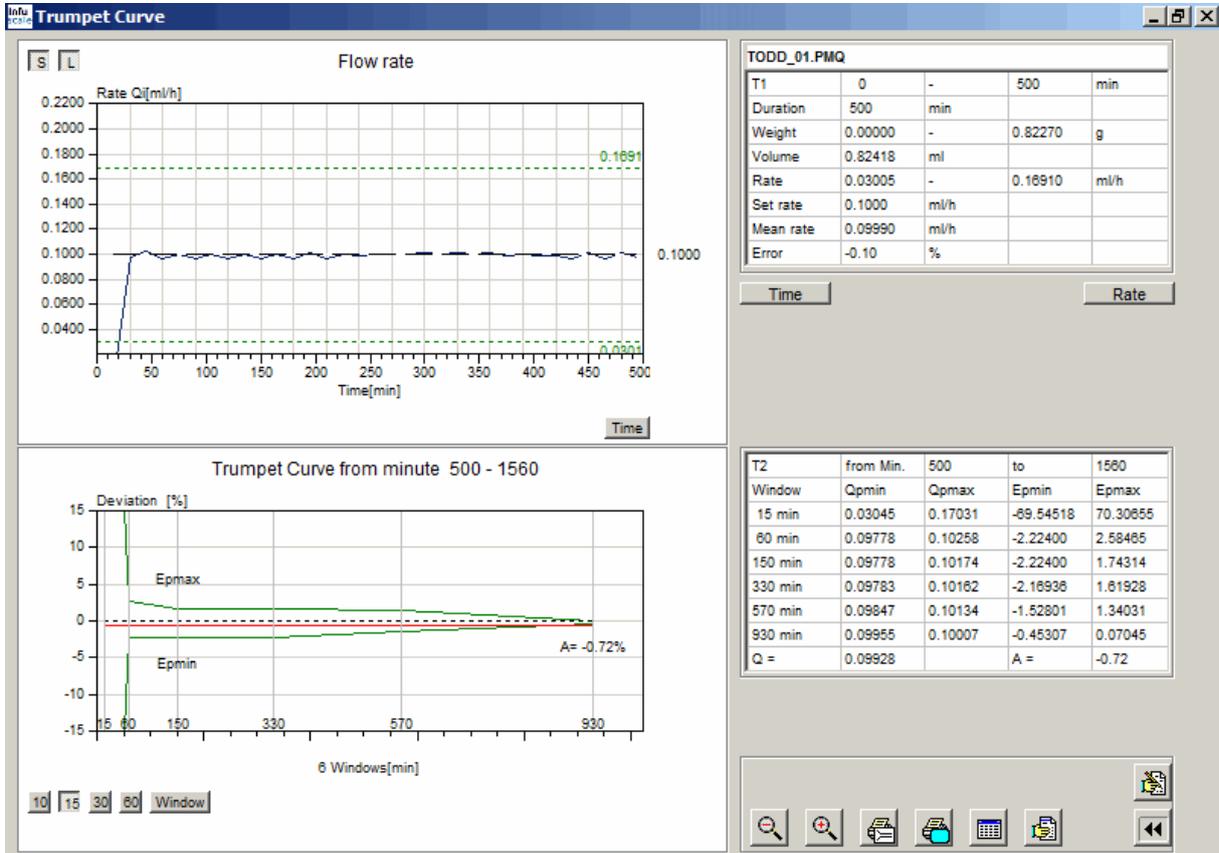


Here the time range for the start-up curve T1 (stabilization period) can be entered. A click on



terminates the input and leads to the graphic display and evaluation of the curves. The points of the flow rate curve each represent mean values over two measured values. The program evaluates the data for the time ranges T1 and T2 according to section 201.12.1.103. The 6 observation intervals here are 15, 60, 150, 330, 570 and 930 minutes.

Figure 17: Trumpet curve for ambulatory use type 1



### 6.3.5 Evaluation of infusion pumps for ambulatory use type 2

Edition 1.0 (1998)		Edition 2.0 (2012)	
Chapter	Key	Chapter	Key
50.105	<b>105</b>	201.12.1.104	<b>104</b>

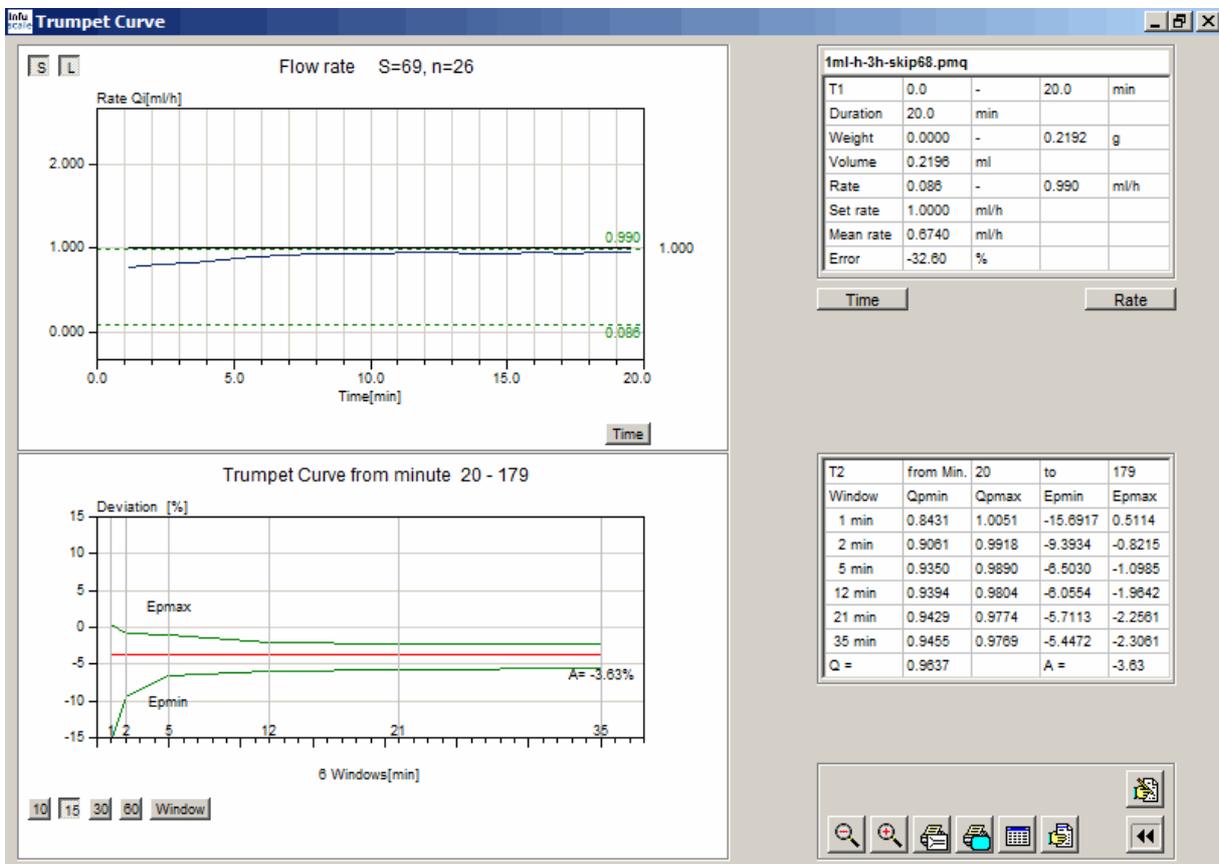
The **105** or **104** key is activated if infusion pumps are to be evaluated for type 2 ambulatory use (see Chapter 4.4). At least 120 measured values must exist here. The specifications in section 50.105 or 201.12.1.104 of the standard apply to the evaluation. The observation intervals used are, depending on the measurement interval S: 1S, 2S, 5S, 11S, 19S and 31S.

After clicking the button, an input line opens at the bottom,

T1 from minute  to  S =  min

with which the time range of the start-up curve T1 (stabilization period) and the measuring interval S can be entered. A click on  terminates the input and leads to the graphic display and evaluation of the curves. The points of the flow rate curve each represent mean values over n measured values, where n multiplied by S results in 30 minutes.

Figure 18: Trumpet curve for ambulatory use type 2



### 6.3.6 The freely adjustable trumpet curve

With the  key, an INFUSCALE file for a freely selectable time range can be calculated and displayed as a trumpet curve in the "Evaluation" screen. The observation intervals are 2, 5, 11, 19 and 31 minutes according to section 50.102 or 201.12.1.102 of the standard. The requirements regarding the minimum duration of the measurement (> 2 hours) do not have to be met.

After clicking, an input line opens at the bottom,



T1 from minute  to  

with which the time range over which the trumpet curve is to be calculated can be entered.

A click on  terminates the input and leads to the graphic display and evaluation.

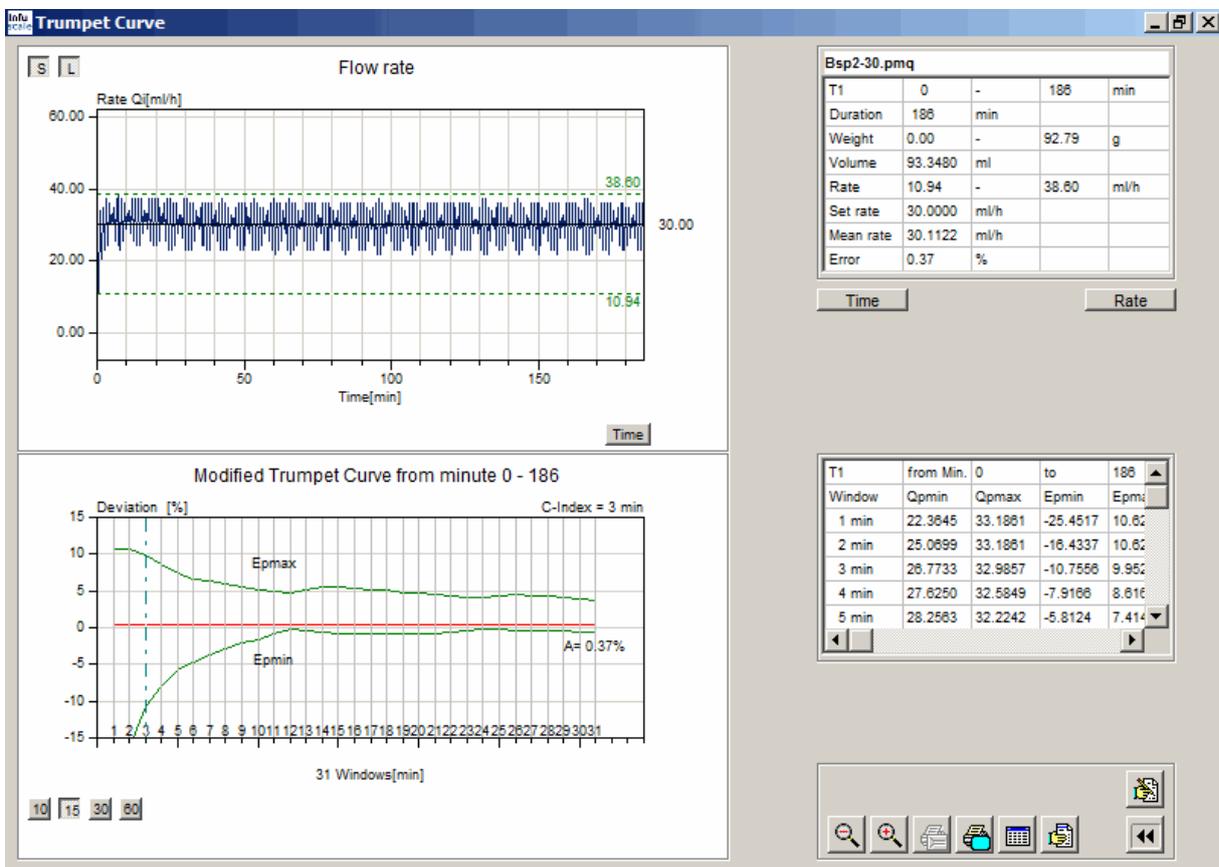
A click on the button  creates a trumpet curve with 6 observation windows, another click creates a trumpet curve with 31 observation windows and a third click creates again the original trumpet curve with 5 observation windows.

### 6.3.7 Modified trumpet curve and constancy index

The constancy index is a measure of the short-term accuracy of an infusion pump. It should be as low as possible for pumps suitable for the administration of strong drugs with a short half-life, i.e. lower than the half-life.

To determine the constancy index, the flow rate of the pump to be examined is measured over 24 hours at a flow rate of 1 mL/h. The measurement interval is 30 seconds. For the last 18 hours, the mean flow rates are calculated in the time windows 1, 2, 3, 4, ... 29, 30 and 31 minutes are calculated. The maximum positive and negative deviations of the flow rates measured in each time window compared to the total mean flow rate represent the points of the modified trumpet curve. In contrast to the trumpet curve according to ISO 60601-2-24, this curve is therefore not based on 5 or 6, but on 31 observation intervals.

Figure 19: Modified trumpet curve and constancy index



The constancy index is the time interval in which the maximum positive and negative deviation from the mean flow rate is less than 10%. In the above example, the constancy index is 3 min. It is represented graphically as a vertical dashed line and displayed as a number above the upper right corner of the trumpet curve.

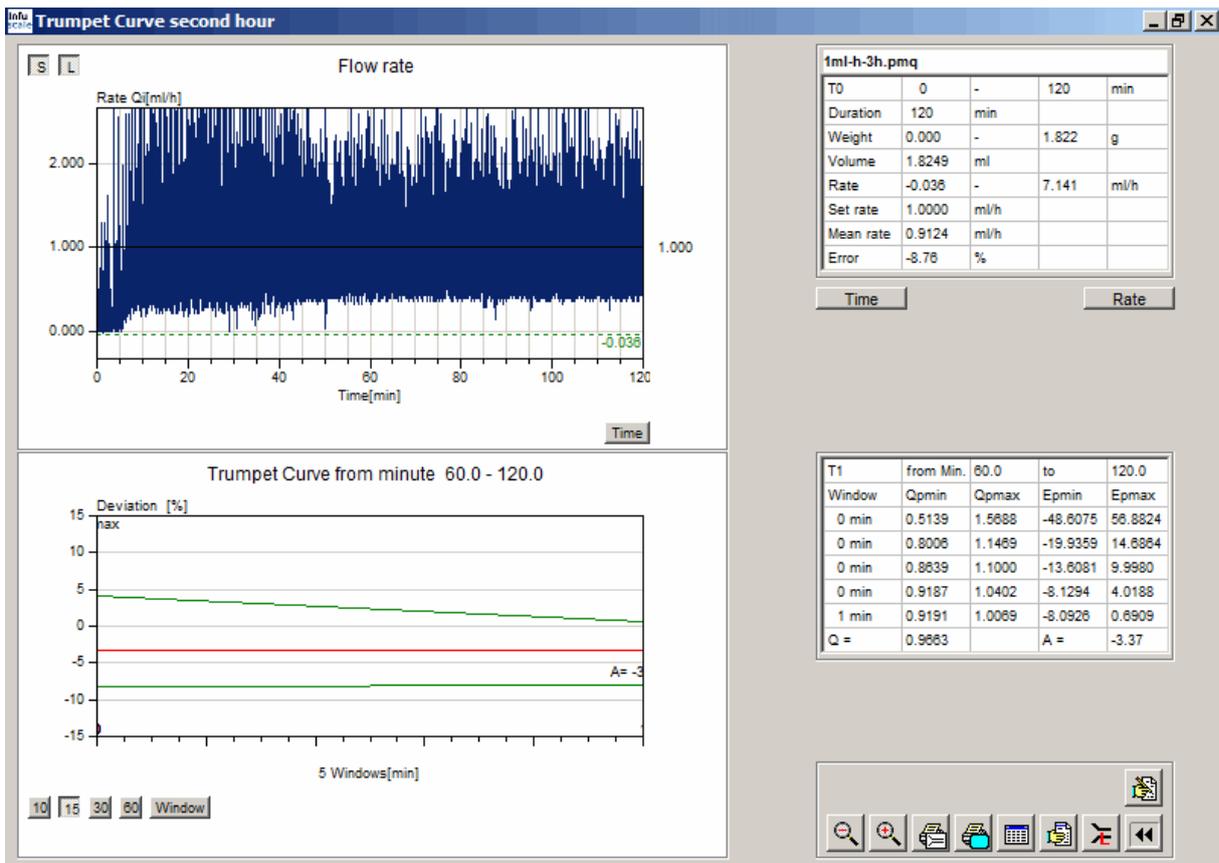
### 6.3.8 Skip function

The skip function serves the purpose of changing an existing INFUSCALE file, whose parameters are unsuitable for the calculation of a trumpet curve, in such a way that a trumpet curve can be created afterwards. For this purpose, a certain adjustable number of data lines are skipped in each case when loading the INFUSCALE file. The remaining data lines form a reduced data set with a larger measuring interval. Optionally, the resulting data set can be saved to a new file.

The number of data lines to be skipped is set in field  in the top line of the evaluation screen (see Figure 12). The measuring interval increases according to this value. If the number is 1, for example, one data line is skipped at a time. Only every second data line is loaded and the measuring interval doubles from originally 1s to 2s. If the number is 29, then 29 data lines are skipped each time they are loaded and the measuring interval increases from 1s to 30s.

The following example deals with the processing of a file with 10800 data lines and a measurement interval of 1 second. Figure 20 shows the evaluation according to 201.12.1.102 of the standard, but without trumpet curve due to the small measurement interval with 4 observation windows of zero minutes.

Figure 20: Trumpet curve of the file 1ml-h-3h before editing



This changes after editing the file using the skip function, as shown in Table 11 as example.

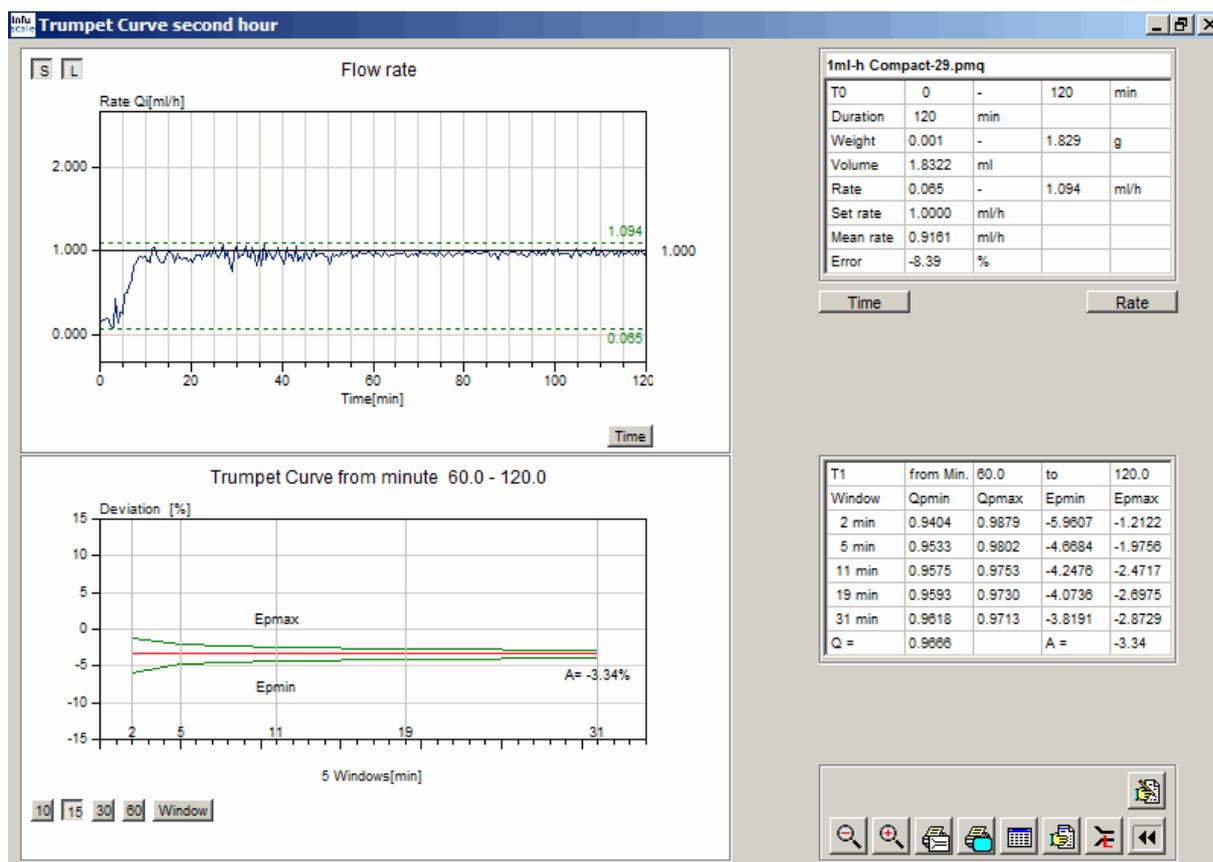
**Table 11: Example skip function**

	File name	Number of data rows	Measuring interval	Error A60-120 min
Original file	1ml-h-3h.pmq	10800	1 s	-3.37%
1 line skipped	1ml-h-3h-skip1.pmq	5399	2 s	-3.37%
9 lines skipped	1ml-h-3h-skip9.pmq	1079	10 s	-3.37%
14 lines skipped	1ml-h-3h-skip14.pmq	719	15 s	-3.37%
29 lines skipped	1ml-h-3h-skip29.pmq	359	30 s	-3.37%

The skip function reduces the number of data lines (values) and increases the measurement interval accordingly. This results in an averaging of the values within a measuring interval. The mean flow error A (see chapter 8) remains constant.

The following graphic shows the evaluation of the file "1ml-h-3h-skip29.pmq", which was created from the original file "1ml-h-3h.pmq" by applying the skip function.

**Figure 21: Trumpet curve of the file 1ml-h-3h after processing**



### 6.3.9 Copy to a new file

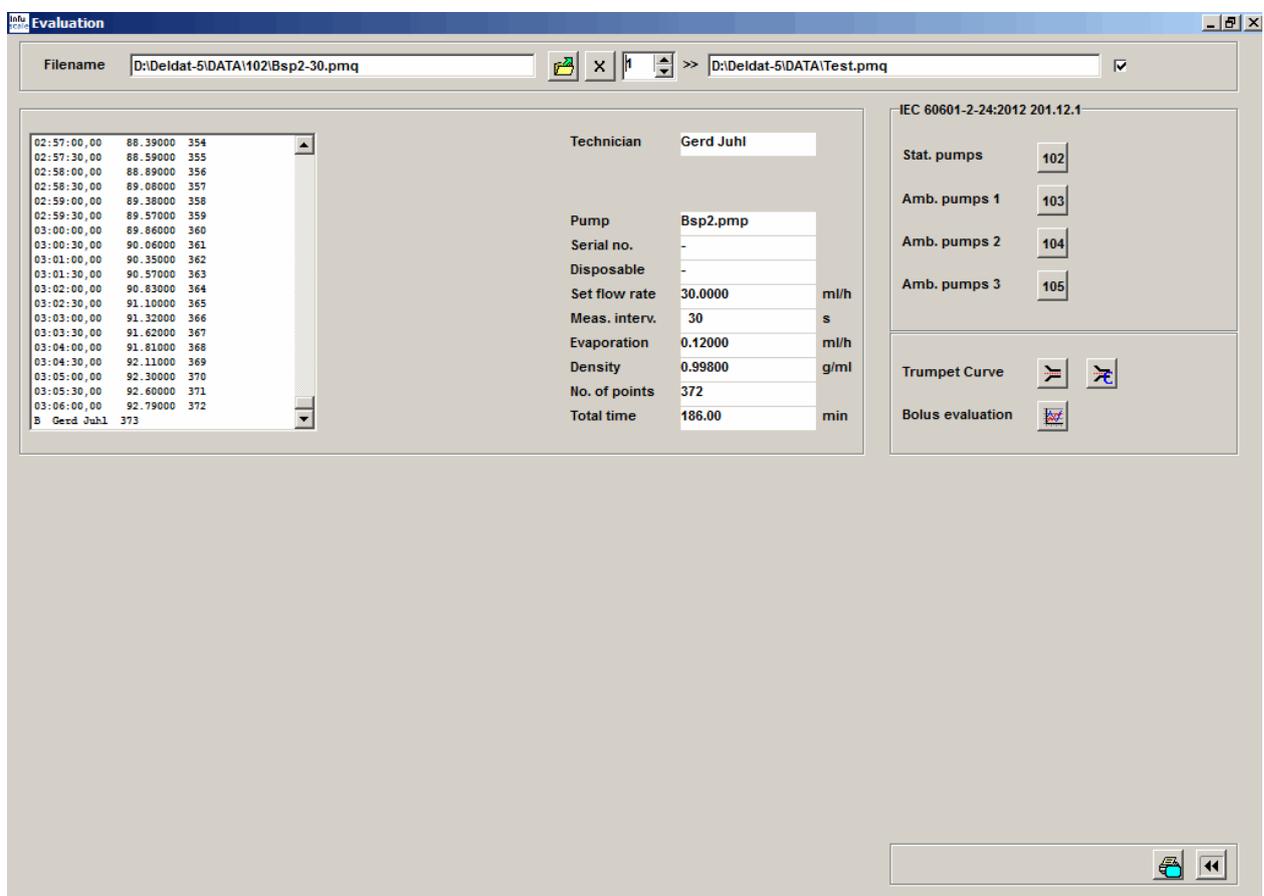
The INFUSCALE file to be loaded can optionally also be copied to a new file. To do this, highlight the "copy"  field in the "Evaluation" screen and type in a new file name. In the following example, the new file is called "Test.pmq". No lines are skipped when loading.



The file "Test.pmq" will be identical to the source file after loading.

In the example on the following page every second data line is skipped, so that the file "Test.pmq" after loading contains only the data lines 1, 3, 5, 7 and so on. The number of values is then only 186 instead of 372 and the measurement interval is 60 s.

Figure 22: Skipping a data row and copying to new file

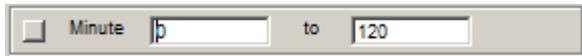


## 6.3.10 Other commands

### 6.3.10.1 Set time range



This key opens an input bar for redefining the time range (X axis).



Clicking the button to the left of "Minute" resets the X-axis to the maximum range.

### 6.3.10.2 Set flow rate range



This key opens an input bar for redefining the flow rate range (Y axis).

Clicking the button to the left of "Rate" resets the Y-axis to the maximum range.

### 6.3.10.3 Zoom function



After clicking this button, a section of the flow rate graph can be displayed enlarged. To determine the zoom area, a rectangle is drawn on the graph with the mouse button pressed. The area located within this rectangle is then displayed enlarged.

### 6.3.10.4 Normal image (Unzoom)



After clicking this button the original size of the graphic will be restored.

### 6.3.10.5 Comment lines input



After clicking this button a comment field opens.



It contains 4 lines which are printed both in the graphic and in the protocol printout. Clicking on  makes the comment field disappear. Clicking on the  key causes the comment lines to be transferred to the comment memory. The entered comment is printed in the protocol.

### 6.3.11 Output functions

#### 6.3.11.1 Printing the trumpet curve



After clicking this button, a printout of the flow rate curve and below it the trumpet curve is made.

#### 6.3.11.2 Screen print



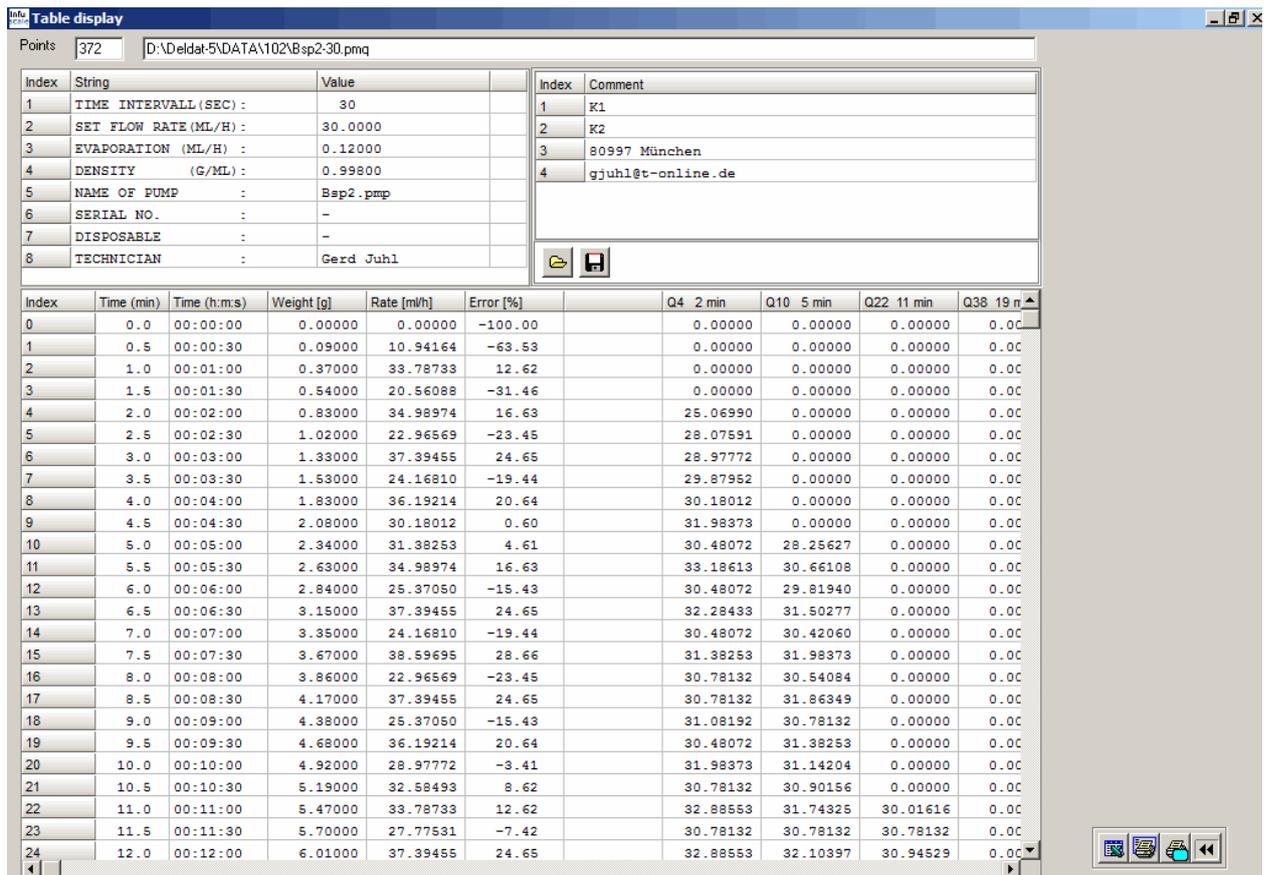
After clicking this button, a screen printout is made.

### 6.3.11.3 Table output

After clicking 

the header lines of the INFUSCALE file, the comment, the individual measured values and the calculated values are displayed in 3 tables. The column "Error[%]" in the lower table shows the percentage error compared to the set flow rate. Columns Q1 to Q62 contain the averaged flow rates. At the end are the evaluations according to the standard.

Figure 23: Table representation trumpet curve



Index	String	Value	Index	Comment
1	TIME INTERVALL (SEC) :	30	1	K1
2	SET FLOW RATE (ML/H) :	30.0000	2	K2
3	EVAPORATION (ML/H) :	0.12000	3	80997 München
4	DENSITY (G/ML) :	0.99800	4	gjuhl@t-online.de
5	NAME OF PUMP :	Bsp2.pmp		
6	SERIAL NO. :	-		
7	DISPOSABLE :	-		
8	TECHNICIAN :	Gerd Juhl		

Index	Time (min)	Time (h:m:s)	Weight [g]	Rate [ml/h]	Error [%]	Q4 2 min	Q10 5 min	Q22 11 min	Q38 19 min
0	0.0	00:00:00	0.00000	0.00000	-100.00	0.00000	0.00000	0.00000	0.00000
1	0.5	00:00:30	0.09000	10.94164	-63.53	0.00000	0.00000	0.00000	0.00000
2	1.0	00:01:00	0.37000	33.78733	12.62	0.00000	0.00000	0.00000	0.00000
3	1.5	00:01:30	0.54000	20.56088	-31.46	0.00000	0.00000	0.00000	0.00000
4	2.0	00:02:00	0.83000	34.98974	16.63	25.06990	0.00000	0.00000	0.00000
5	2.5	00:02:30	1.02000	22.96569	-23.45	28.07591	0.00000	0.00000	0.00000
6	3.0	00:03:00	1.33000	37.39455	24.65	28.97772	0.00000	0.00000	0.00000
7	3.5	00:03:30	1.53000	24.16810	-19.44	29.87952	0.00000	0.00000	0.00000
8	4.0	00:04:00	1.83000	36.19214	20.64	30.18012	0.00000	0.00000	0.00000
9	4.5	00:04:30	2.08000	30.18012	0.60	31.98373	0.00000	0.00000	0.00000
10	5.0	00:05:00	2.34000	31.38253	4.61	30.48072	28.25627	0.00000	0.00000
11	5.5	00:05:30	2.63000	34.98974	16.63	33.18613	30.66108	0.00000	0.00000
12	6.0	00:06:00	2.84000	25.37050	-15.43	30.48072	29.81940	0.00000	0.00000
13	6.5	00:06:30	3.15000	37.39455	24.65	32.28433	31.50277	0.00000	0.00000
14	7.0	00:07:00	3.35000	24.16810	-19.44	30.48072	30.42060	0.00000	0.00000
15	7.5	00:07:30	3.67000	38.59695	28.66	31.38253	31.98373	0.00000	0.00000
16	8.0	00:08:00	3.86000	22.96569	-23.45	30.78132	30.54084	0.00000	0.00000
17	8.5	00:08:30	4.17000	37.39455	24.65	30.78132	31.86349	0.00000	0.00000
18	9.0	00:09:00	4.38000	25.37050	-15.43	31.08192	30.78132	0.00000	0.00000
19	9.5	00:09:30	4.68000	36.19214	20.64	30.48072	31.38253	0.00000	0.00000
20	10.0	00:10:00	4.92000	28.97772	-3.41	31.98373	31.14204	0.00000	0.00000
21	10.5	00:10:30	5.19000	32.58493	8.62	30.78132	30.90156	0.00000	0.00000
22	11.0	00:11:00	5.47000	33.78733	12.62	32.88553	31.74325	30.01616	0.00000
23	11.5	00:11:30	5.70000	27.77531	-7.42	30.78132	30.78132	30.78132	0.00000
24	12.0	00:12:00	6.01000	37.39455	24.65	32.88553	32.10397	30.94529	0.00000

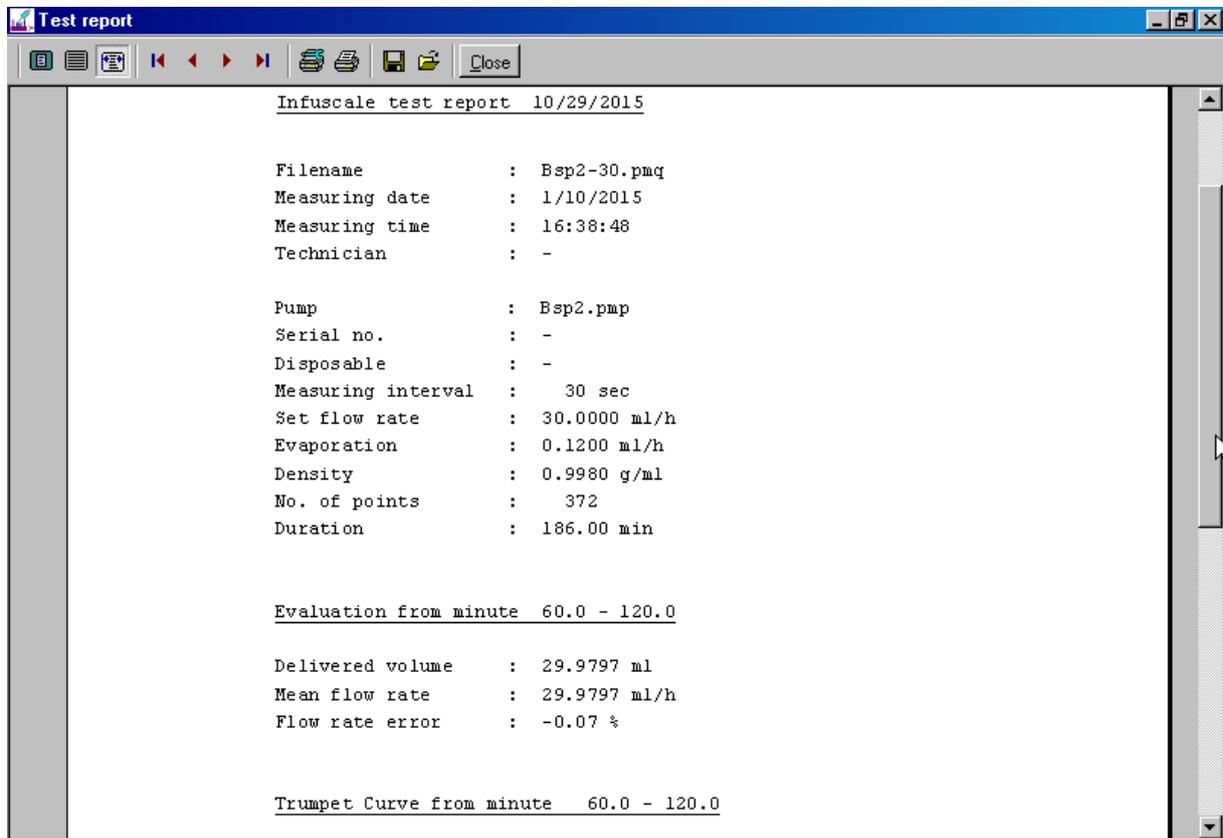
A printout of the lower table can be made with . The screen printout is possible with . Clicking  allows saving the table as an Excel file. The keys   are used to load and save the comment lines.

### 6.3.11.4 Protocol output



After clicking this button, the INFUSCALE measurement protocol (test report) is displayed.

Figure 24: Protocol trumpet curve



With  this protocol can be printed. Clicking the button  allows saving as a file either in TXT, WMF, HTML, CSV, RTF or XLS format. An adoption by Microsoft Word and Excel is thus easily possible.

### 6.3.11.5 Storage of Graphics on File and to Clipboard

If the cursor is located on one of the two graphs, the following menu can be displayed by clicking the right mouse button:



The left mouse button is now used to save the respective graphic as a file in bitmap or JPG format. With "CopyToClipboard" the graphic can be saved to the clipboard, which makes it easy to paste it into a text program.

Note: Auxiliary lines are not stored with the image.

## 6.4 The bolus evaluation

### 6.4.1 Evaluation of infusion pumps for ambulatory use type 3

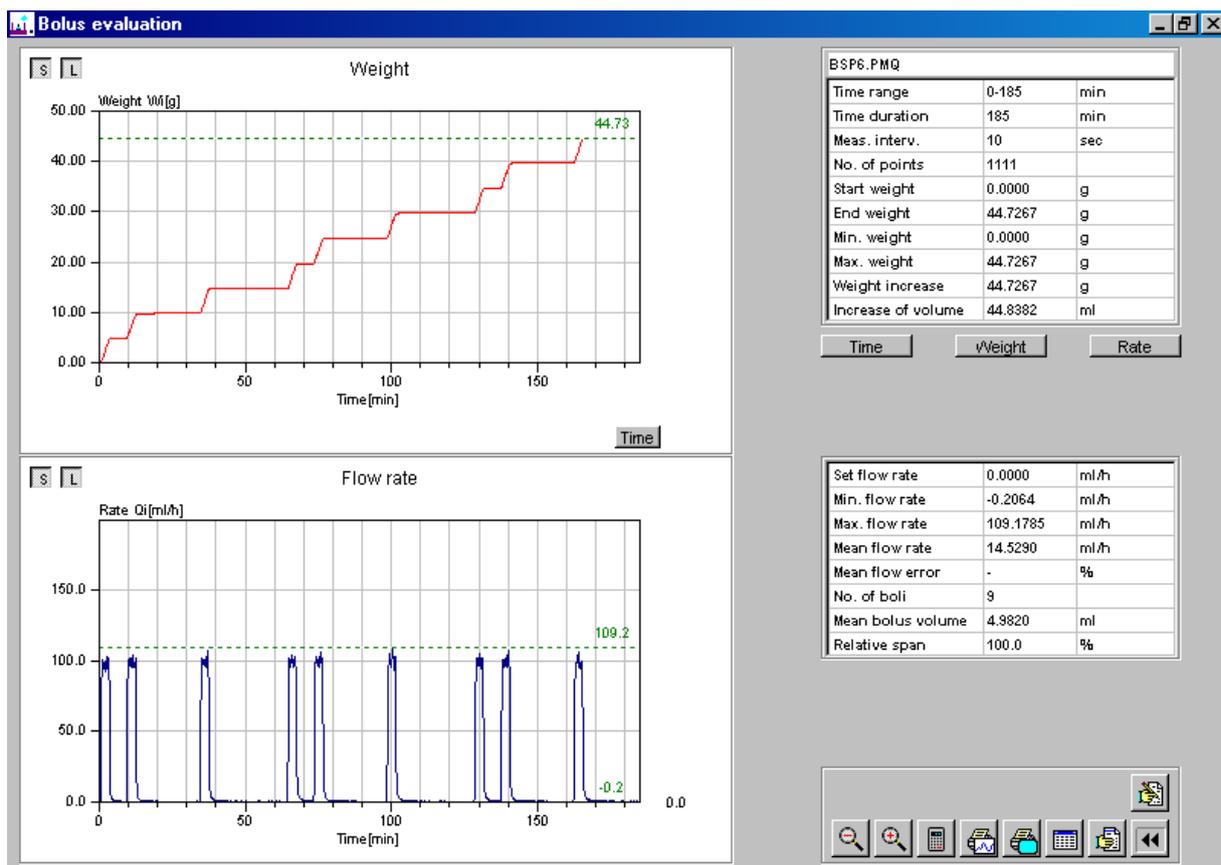
Edition 1.0 (1998)		Edition 2.0 (2012)	
Chapter	Key	Chapter	Key
50.106	<b>106</b>	201.12.1.105	<b>105</b>

After clicking the **106** or **105** key in the "Evaluation" screen, a program section is called up which is particularly suitable for evaluating infusion pumps for ambulatory use type 3, i.e. pumps with bolus characteristics (section 50.106 or 201.12.1.105 of the standard). No trumpet curve is calculated, but weight and flow rate are displayed graphically below each other.

This will be shown with an example.

In the "Evaluation" screen, the file BSP6.PMQ was selected and then the button **105** was clicked. The following graphic appears:

Figure 25: Bolus evaluation



In the upper part of the screen, the weight of the pumped liquid is plotted over time. At the bottom left is the start weight and at the top right is the end weight. To the right of the curve, the minimum weight and the maximum weight are indicated as numbers (here 0.0000 and 44.7267, respectively).

The stair steps as an expression of the flow of limited liquid volumes (boli) with a high flow rate are clearly visible in the curve. A total of 9 liquid boluses were delivered in this example.

The lower part of the screen shows the course of the flow rate, plotted over time. You can see the steep increase during a step and its decrease in the time between two boluses. To the right of the curve, the minimum and maximum rates are indicated as numbers (here -0.2 and 109.2, respectively).

With the key **S** in the upper left corner of the picture the scaling of the Y-axis can be changed. If this key is not pressed, the Y-range of the curve corresponds exactly to the Y-value range of the measurement with corresponding odd Y-subdivisions. If **S** is pressed, the curve is drawn so that the maximum value of Y is the next even value above the Y maximum. The Y subdivisions are integer.

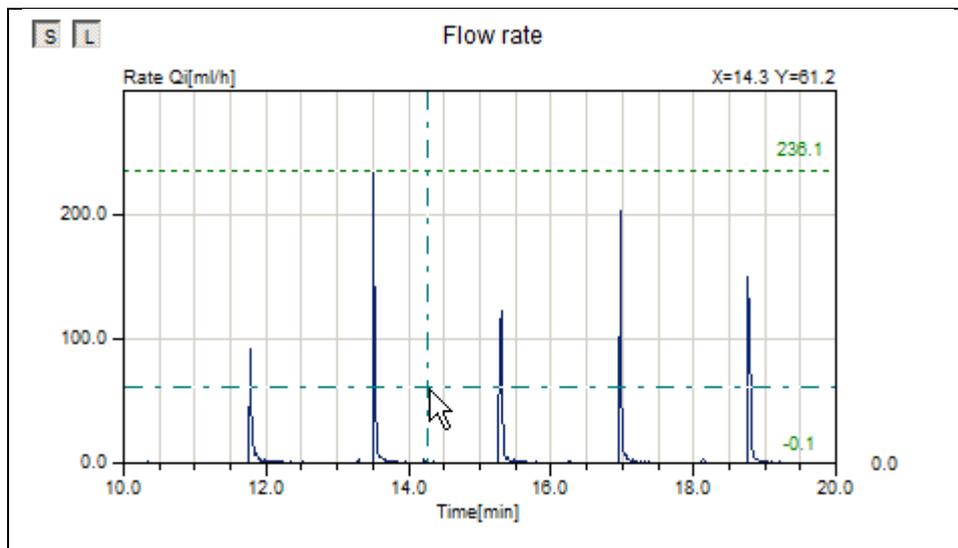
If the key **L** pressed, a dashed line appears in the flow rate curve at the height of the maximum or minimum rate.

The two fields on the right side of the screen contain the calculated data as numbers.

### 6.4.2 Acquisition small boli

In order to also detect very small boluses, which may not be taken into account in the automatic detection, please click on the "Flow rate" graphic while holding down the left mouse button. Under the cursor, if you move it a little, a vertical and a horizontal dashed line will appear. The cursor is now dragged down so far that the accompanying horizontal line is below the tip of the smallest bolus (see next image).

Figure 26: Detection of small boluses



### 6.4.3 Bolus evaluation with adjustable time range

By clicking the  button in the "Evaluation" screen, an INFUSCALE file can be calculated and displayed in a freely selectable time range.

An input line opens at the bottom where the time range can be entered.



The image shows a horizontal input field with a grey background. On the left, the text "T1 from minute" is followed by a small blue square containing the number "0". To the right of this is the word "to", followed by a white rectangular box containing the number "186.00". On the far right of the input field is a small square button containing a black left-pointing arrow.

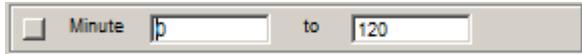
A click on  terminates the input and leads to the graphic display and evaluation.

## 6.4.4 Other commands

### 6.4.4.1 Set time range



This key opens an input bar for redefining the time range (X axis).



Clicking the button to the left of "Minute" resets the X-axis to the maximum range.

### 6.4.4.2 Set weight range



This key opens an input bar for redefining the weight range (Y axis).

Clicking the button to the left of "Weight" resets the Y-axis to the maximum range.

### 6.4.4.3 Set flow rate range



This key opens an input bar for redefining the flow rate range (Y axis).

Clicking the button to the left of "Rate" resets the Y-axis to the maximum range.

### 6.4.4.4 Zoom



After clicking this button, sections of the graphics can be displayed enlarged. To determine the zoom area, a rectangle is drawn on the graphic with the mouse button pressed. The area within this rectangle will then be displayed in both graphs, regardless of which graph the rectangle was drawn in.

### 6.4.4.5 Normal image (Unzoom)



After clicking this button the original size of the graphic will be restored.

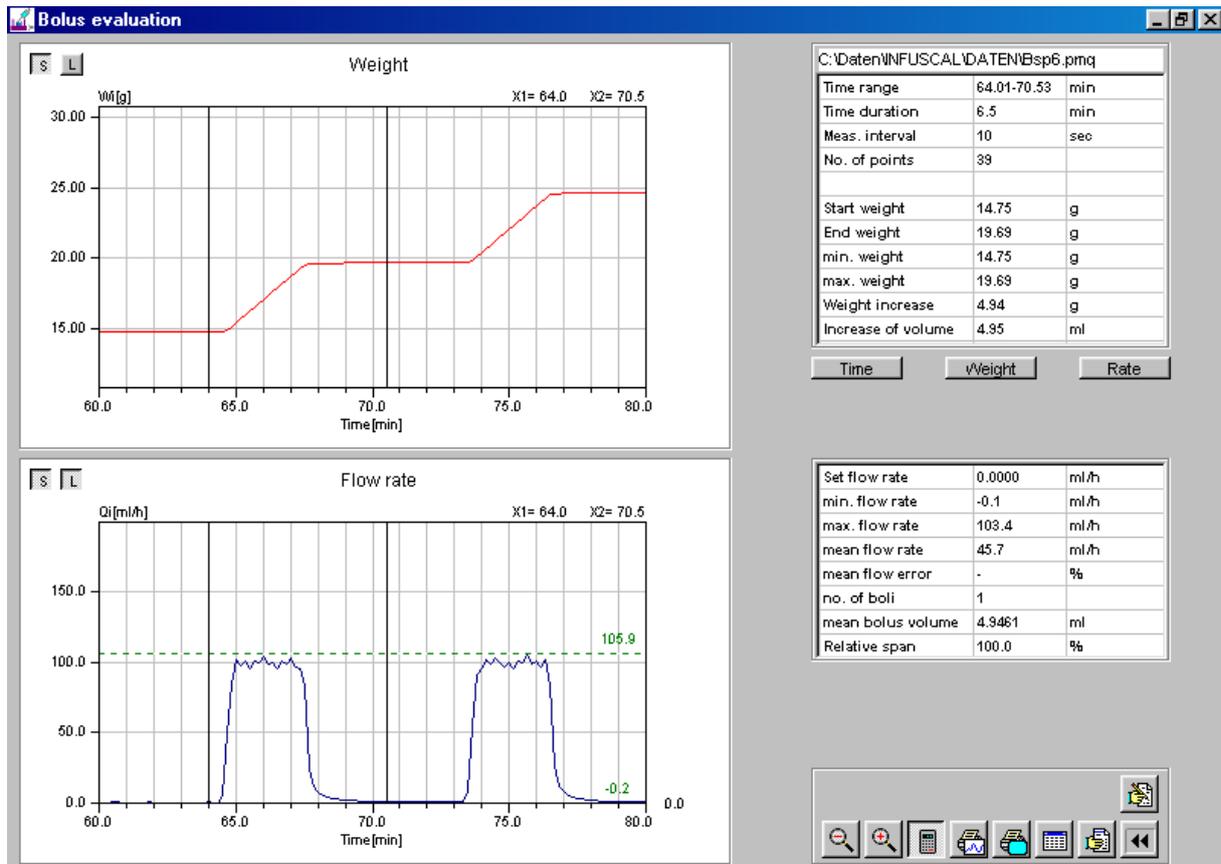
### 6.4.4.6 Graph measurement



After clicking this button, a measurement of the graph can be made. With the left mouse button pressed, first the left vertical line is moved to that point of the curve which is to be the lower measurement limit. Then, by moving the right vertical line, the upper survey boundary is defined. INFUSCALE recalculates each time the values between lower and upper limit and displays them in both list areas of the screen.

#### Example

Figure 27: Bolus measurement



This example shows the file Bsp6.pmq, where after clicking on **Time** a section enlargement between minute 60 and 80 was made. Then the area between minute 64.01 and 70.53 was measured. In the list box it can be read, among other things, that the mean flow rate between the two lines is 45.7 mL/h and the bolus between the two vertical lines has a volume of 4.9461mL. The maximum flow rate between the lines is 103.4 mL/h, and it is 105.9 mL/h in the entire displayed range.

### 6.4.4.7 Comment lines input



After clicking this button a comment field opens.



It contains 4 lines which are printed both in the graphic and in the protocol printout. Clicking on  makes the comment field disappear. Clicking on the  key causes the comment lines to be transferred to the comment memory. The entered comment is printed in the protocol.

## 6.4.5 Output functions

### 6.4.5.1 Printing the graphics



After clicking this button, a printout of the graphs will be made.

### 6.4.5.2 Screen print



After clicking this button, a screen printout is made.

### 6.4.5.3 Table output



After clicking this button, the headers of the file, the comment, the individual measured values, the corresponding flow rates and evaluations are displayed in 3 tables. At the end of table 3 are the evaluations.

Figure 28: Table display of bolus evaluation

Index	String	Value	Index	Comment
1	TIME INTERVALL (SEC) :	10	1	
2	SET FLOW RATE (ML/H) :	0.0000	2	
3	EVAPORATION (ML/H) :	0.01000	3	
4	DENSITY (G/ML) :	0.99820	4	
5	NAME OF PUMP :	PCA-Beispiel		
6	SERIAL NO. :	0123/9		
7	DISPOSABLE :	-		
8	TECHNICIAN :	-		

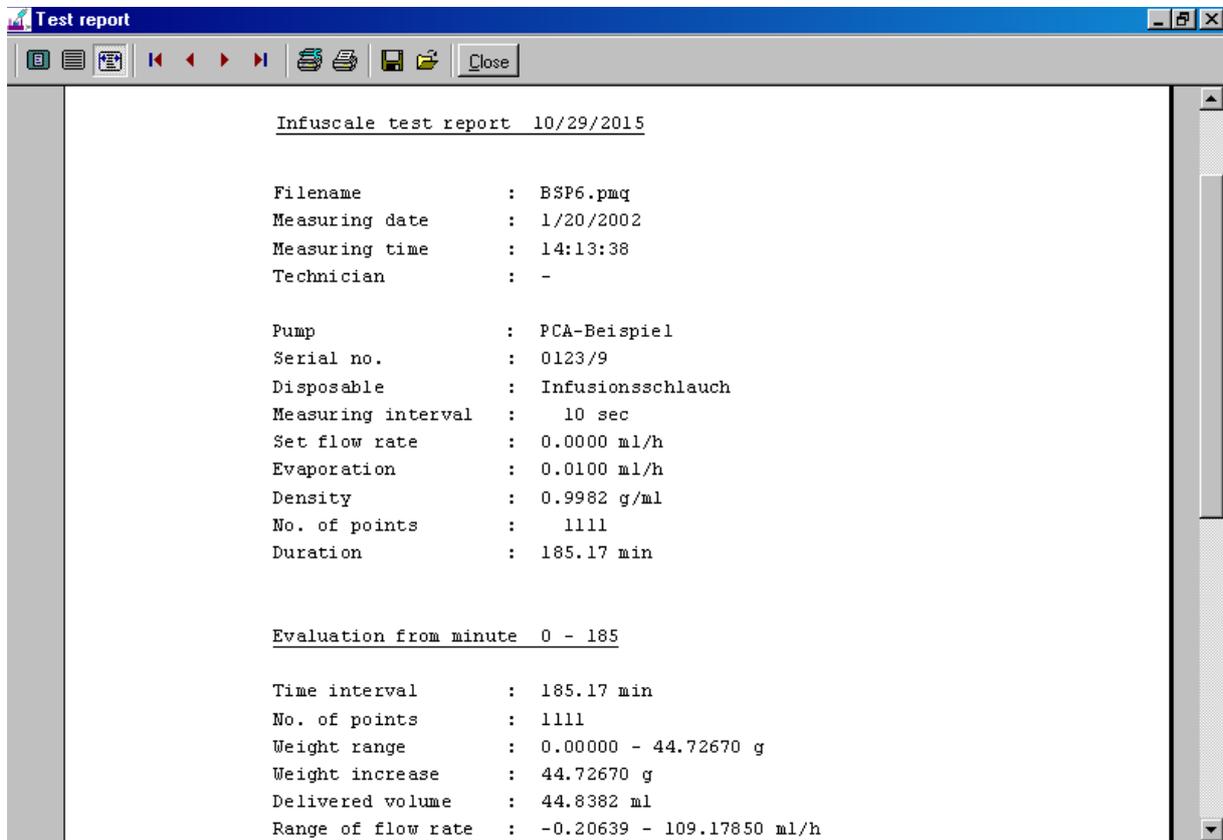
Index	Time (min)	Time (h:m:s)	Weight [g]	Rate [ml/h]	Weight	Rate	Event
0	0.0	00:00:00	0.00000	0.00000	min		
1	0.2	00:00:10	0.00030	0.11819			
2	0.3	00:00:20	0.00060	0.11819			
3	0.5	00:00:30	0.01950	6.82627			
4	0.7	00:00:40	0.22640	74.62831			
5	0.8	00:00:50	0.50450	100.30653			
6	1.0	00:01:00	0.77110	96.16907			
7	1.2	00:01:10	1.01760	88.91002			
8	1.3	00:01:20	1.28830	97.63773			
9	1.5	00:01:30	1.56200	98.71968			
10	1.7	00:01:40	1.83640	98.97213			
11	1.8	00:01:50	2.09590	93.59846			
12	2.0	00:02:00	2.35810	94.57221			
13	2.2	00:02:10	2.61270	91.83128			
14	2.3	00:02:20	2.88860	99.51311			
15	2.5	00:02:30	3.16270	98.86394			
16	2.7	00:02:40	3.44820	102.97534			
17	2.8	00:02:50	3.71300	95.50990			
18	3.0	00:03:00	3.97150	93.23781			
19	3.2	00:03:10	4.25420	101.96552			
20	3.3	00:03:20	4.53320	100.63112			
21	3.5	00:03:30	4.73270	71.95951			

A printout of the table can be made with The screen printout is possible with Clicking allows saving the table as an Excel file. The keys are used to load and save the comment lines.

### 6.4.5.4 Measurement protocol

After clicking this button, the INFUSCALE measurement protocol (test report) is displayed.

Figure 29: Bolus evaluation protocol



With  this protocol can be printed. Clicking the button  allows to save it as a file either in TXT, WMF, HTML, CSV, RTF or XLS format.

### 6.4.5.5 Storage of Graphics on File and to Clipboard

If the cursor is located on one of the two graphs, the following menu can be displayed by clicking the right mouse button:



The left mouse button is now used to store the respective graphic as a file in bitmap or JPG format. With "CopyToClipboard" the graphic can be stored to the clipboard, which makes it easy to paste it into a text program.

Note: Auxiliary lines are not stored with the image.

## 7 MEASUREMENT ERROR

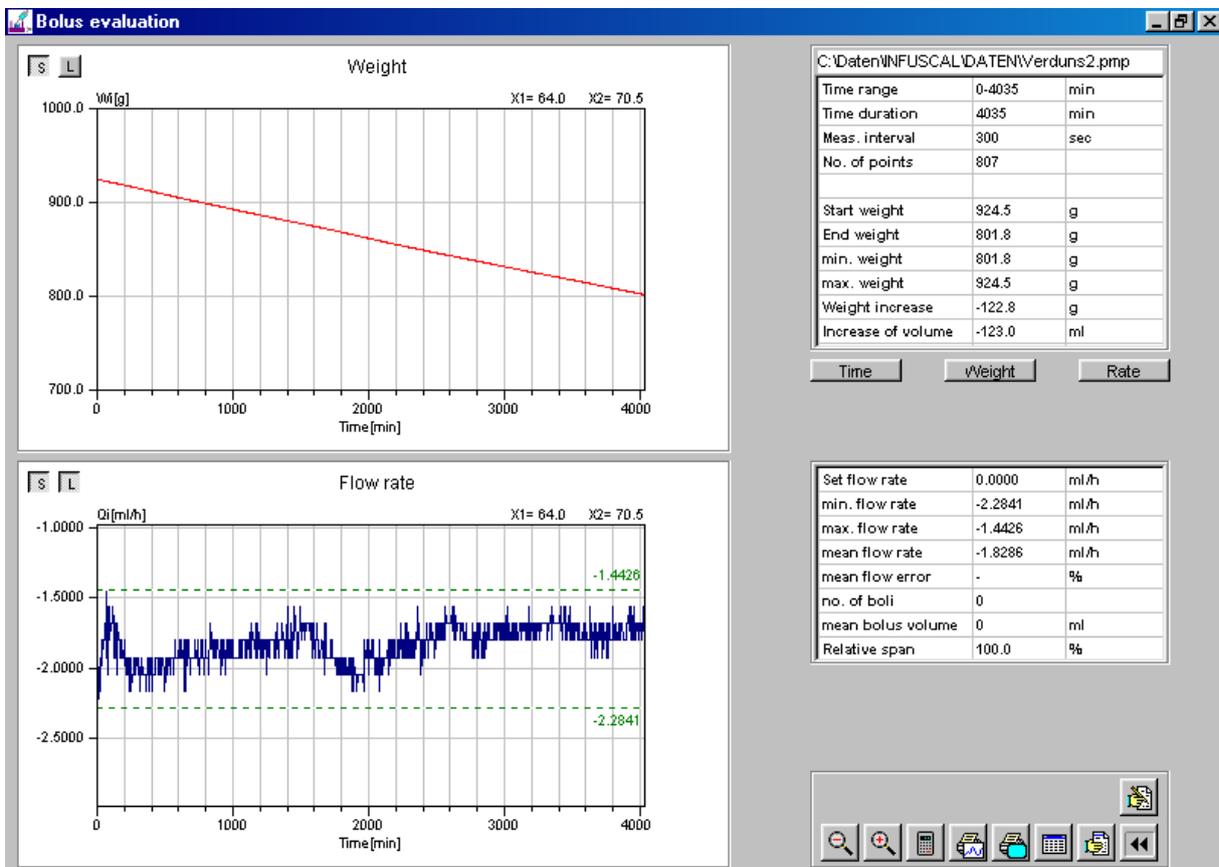
At this point, the influence of evaporation and the interrogation error resulting from automatic data acquisition via scale and computer will be discussed.

Other errors such as the cannula effect based on the buoyancy of the cannula, the influence of temperature and latitude on the measurement accuracy play only a minor role and will not be discussed here.

### 7.1 Evaporation

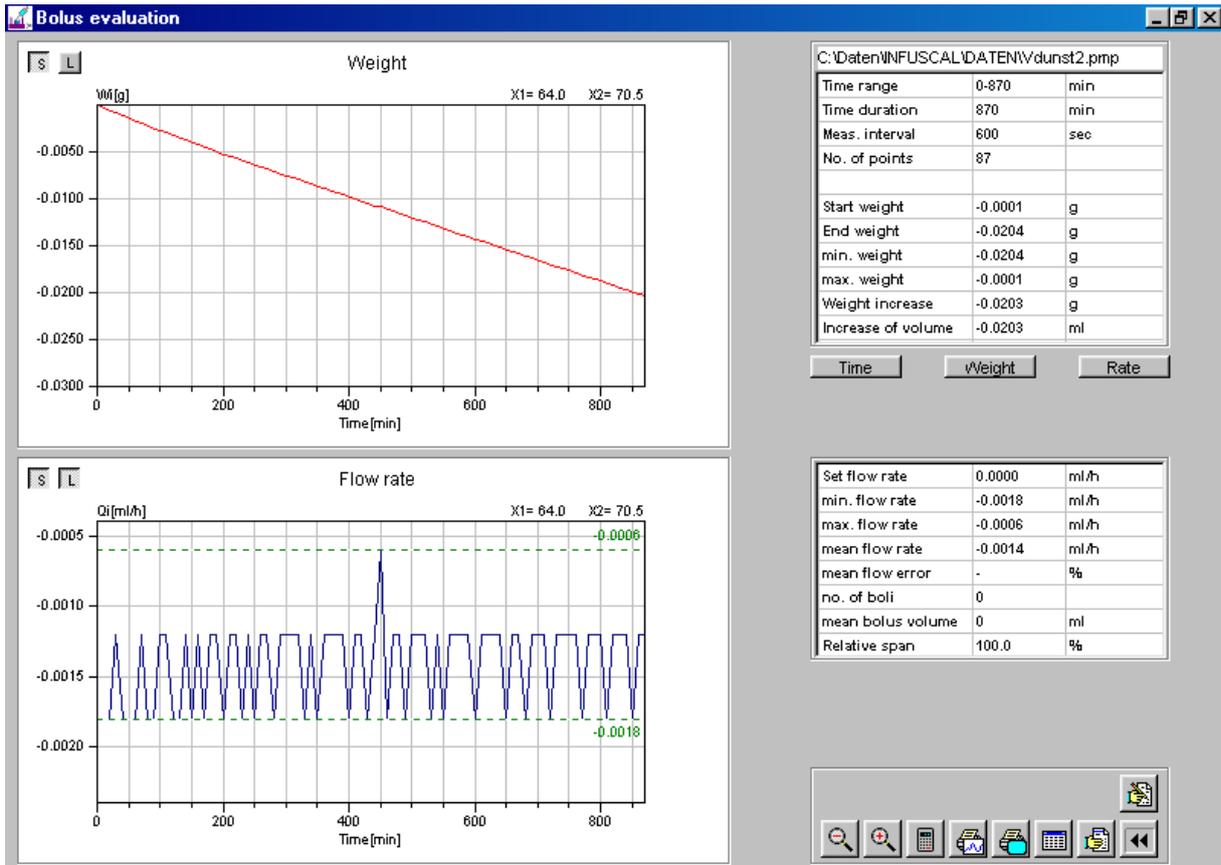
The effect of evaporation is illustrated by the following two graphs:

Figure 30: Evaporation without oil layer



In this first measurement, the evaporation container was a household bucket with a capacity of 4 liters without an oil layer. Within 67 hours, 122.8 mL of water evaporated. The gradual decrease in the weight of the bucket over time can be clearly seen in the upper graph. Correspondingly, the evaporation curve at the bottom ranges between -2.2841 and -1.4426. The average evaporation rate is -1.8286 mL/h.

Figure 31: Evaporation with oil layer



The container used for this second measurement held approximately 100 mL. An oil layer was used. Within 870 minutes, 0.02 mL of water evaporated. The evaporation rate calculated from this is -0.0014 mL/h on average.

These two examples show that the effect of evaporation can lead to larger measurement errors. Therefore, it is recommended to work with an oil layer in principle for precise measurements or for measurements of pumps with a small flow rate. In a pre-run, the evaporation rate can be determined and this can be entered into the program before starting the measurement (see chapter 5.2.1).

## 7.2 Interrogation error

Provided that the operating system is set correctly as described in 3.1, the error of the PC timer is one to two orders of magnitude below the interrogation error and can be neglected here.

### 7.2.1 Mettler scale AE 100 (continuous operation)

The Mettler scale AE100 periodically sends a data record to the computer in continuous operation (Mettler auto). The time interval between two data transmissions is a maximum of 440 ms. The interrogation by the computer takes place in each case after the expiry of the entered measuring interval and is not synchronized, so that the interrogation time can be shifted by a maximum of 440 ms. This means that the computer takes a weight value that was present a maximum of 440 ms before the actual query time. With a standard measuring interval of 30 sec, the error is a maximum of 1.5 %.

When determining the trumpet curve, 4 to 62 measured values are averaged. This reduces the error to a maximum of 0.38 %.

The following table shows the max. interrogation error and the averaged error resulting for the smallest observation window  $p = 2$  min of the trumpet curve as a function of the measurement interval. The indicated maximum errors are extreme values.

**Table 12: Maximum error depending on the measuring interval - Mettler auto**

Measuring interval	max. query error	mean error (p=2min)
1 s	44%	11%
3 s	14.6%	3.7%
6 s	7.3%	1.8%
10 s	4.4%	1.1%
30 s	1.5%	0.38%
60 s	0.73%	0.18%
100 s	0.44%	0.11%
300 s	0.15%	0.04%
600 s	0.07%	0.02%
900 s	0.05%	0.01%

### 7.2.2 Sartorius scale MC1 (automatic data output)

In continuous operation (Sartorius auto), the Sartorius MC1 scale periodically sends a data record to the computer. The time interval between two data transmissions is a maximum of 220 ms. The computer polls the data after the measuring interval entered has elapsed and is not synchronized, so that the polling time can be shifted by a maximum of 220 ms. The following table shows the max. query error and the averaged error resulting for the smallest observation window  $p = 2 \text{ min}$  of the trumpet curve as a function of the measurement interval.

**Table 13: Maximum error depending on the measuring interval - Sartorius auto**

Measuring interval	max. query error	mean error (p=2min)
1 s	22%	5.5%
3 s	7.3%	1.8%
6 s	3.6%	0.9%
10 s	2.2%	0.6%
30 s	0.73%	0.18%
60 s	0.36%	0.09%
100 s	0.22%	0.06%
300 s	0.07%	0.02%
600 s	0.04%	0.01%
900 s	0.02%	0.005%

### 7.2.3 Sartorius scale MC1 (request mode)

The Sartorius MC1 scale is interrogated in the request mode (Sartorius requ) after the set measuring interval has elapsed and sends a data record back to the computer as a response. A maximum value of 60 ms was measured as a query error. Realistically, 30 ms is to be expected. This results in low error rates even with small measuring intervals, so that this operating mode is particularly suitable when boluses with short measuring intervals are to be measured.

**Table 14: Maximum error depending on the measuring interval - Sartorius requ**

Measuring interval	max. query error	mean error (p=2min)
1 s	6%	1.5%
3 s	2%	0.5%
6 s	1%	0.25%
10 s	0.6%	0.15%
30 s	0.2%	0.05%
60 s	0.1%	0.03%
100 s	0.06%	0.02%
300 s	0.02%	0.005%
600 s	0.01%	0.002%
900 s	0.005%	0.001%

## 8 EXPLANATION OF SYMBOLS AND FORMULAS

T	Total measuring time in minutes $T = t_k - t_1$ [min]
k	Number of measuring points
r	Set delivery rate [mL/h]
i	Measuring index $i = 1$ to $k$
$\Delta t$	Time interval [min] between two consecutive measuring points
$t_i$	Measuring time [min] at point $i$
p	Observation window index with $p = 4, 10, 22, 38, 62$
$t_{p,i}$	Observation window with $t_{p,i} = t_{i+p} - t_i = p \cdot \Delta t$
$W_i$	Weight [g] at the measuring point $i$ corrected by the evaporation loss
d	Density of water = 0.998 [g/mL] at 20 °C
$Q_i$	Flowrate [mL/h] between two consecutive measuring points $Q_i = \frac{60 \cdot (W_i - W_{i-1})}{d \cdot \Delta t}$
$W_{p,i}$	Weight [g] delivered during the observation window $t_{p,i}$ $W_{p,i} = W_{i+p} - W_i$
W	Total weight [g] delivered during the total time T corrected by the evaporation loss $W = W_k - W_0$
Q	Average flowrate [mL/h] during the total time T $Q = \frac{60 \cdot W}{d \cdot T}$
$Q_{p,i}$	flowrate [mL/h] during the observation window $t_{p,i}$ $Q_{p,i} = \frac{60 \cdot W_{p,i}}{d \cdot t_{p,i}}$

$Q_{pmax}$	Maximum $Q_{p,i}$ [mL/h] for each observation window $t_{p,i}$ and each value of $p$
$Q_{pmin}$	Minimum $Q_{p,i}$ [mL/h] for each observation window $t_{p,i}$ and each value of $p$
$E_{pmax}$	Highest positive deviation of $Q_{pmax}$ for each $p$ , expressed as percentage deviation from the set rate $r$ $E_{pmax} = \frac{Q_{pmax} - r}{r} \cdot 100 \%$
$E_{pmin}$	Highest negative deviation of $Q_{pmax}$ for each $p$ , expressed as percentage deviation from the set rate $r$ $E_{pmin} = \frac{Q_{pmin} - r}{r} \cdot 100 \%$
A	Percentage total error of the average flow rate $Q$ , related to the set rate $r$ during the total time $T$ $A = \frac{Q - r}{r} \cdot 100 \%$