

**Linearity test kit, glucose / lactate, 2 mmol/L, 7 mmol/L, 18 mmol/L**  
**Diluted 51-fold, ready for use**

**Intended Use:**

For in vitro diagnostic use with BIOSEN and EBIO glucose and lactate enzymatic instruments. Also for non-diagnostic use. Not for food or drug use.

**Handling Instructions:**

Set-Lin-Test Glucose/Lactate can be used for linearity or calibration verification studies. Place the micro test tube in a sample position of the sample tray and start measurement as usual.

**Chemical Composition:**

0,039 mmol/L Lactate (2 mmol/L diluted 51-fold),  
 0,137 mmol/L Lactate (7 mmol/L diluted 51-fold) and  
 0,353 mmol/L Lactate (18 mmol/L diluted 51-fold)  
 in a phosphate buffered solution (pH 7.2) containing further ingredients.

**Warning:**

Avoid contact with eyes and skin. Do not swallow.  
 Keep away from foodstuff, beverages and food.

**After skin contact rinse with water. After eye contact rinse opened eye under running water. If symptoms persist, consult doctor.**

**Values:**

<b>REF</b>	Item-No.:	<b>0209-0102-391</b>	3x 1 mL 2 mmol/L in micro test tubes blue 3x 1 mL 7 mmol/L in micro test tubes green 3x 1 mL 18 mmol/L in micro test tubes red
<b>LOT</b>	Charge-No.:		see label
	Expiry date unopened:		see label
	Storage temperature:		Discard if expiration date is past. 2 °C – 8 °C
	Stability after opening:		8 hours (15 °C – 25 °C)

Mean Glucose	Range
2.00 mmol/L 36.0 mg/dL	1.80 – 2.20 mmol/L 32.4 – 39.6 mg/dL
7.00 mmol/L 126.1 mg/dL	6.75 – 7.25 mmol/L 121.6 – 130.6 mg/dL
18.00 mmol/L 324.1 mg/dL	17.50 – 18.5 mmol/L 315.1 – 333.1 mg/dL

Mean Lactate	Range
2.00 mmol/L 18.0 mg/dL	1.80 – 2.20 mmol/L 16.2 – 19.8 mg/dL
7.00 mmol/L 63.1 mg/dL	6.75 – 7.25 mmol/L 60.8 – 65.3 mg/dL
18.00 mmol/L 162.1 mg/dL	17.50 – 18.5 mmol/L 157.6 – 166.7 mg/dL

**Линейный тест, набор, глюкоза/лактат, 2 ммол/л, 7 ммол/л, 18 ммол/л**  
**Разведено в 51 раз, готово к использованию**

**Используется для:**

in vitro диагностики с приборами BIOSEN с EBIO для измерения глюкозы и лактата. Так же допускается использование не для диагностических целей. Не использовать для исследования продуктов питания и лекарств.

**Инструкция по применению:**

Линейный тест используется для проверки линейности и контроля калибровки приборов. Поместите пробирку с линейным тестом в карусель на измерительную позицию и начните измерение как обычно.

**Химический состав:**

0,039 ммол/л глюкоза/лактата ( 2 ммол/л разведено в 51 раз),  
 0,137 ммол/л глюкоза/лактата ( 7 ммол/л разведено в 51 раз),  
 0,353 ммол/л глюкоза/лактата (18 ммол/л разведено в 51 раз)  
 Растворы разведены в фосфатном буфере (pH 7.2).

**Внимание:**

Избегать попадания в глаза и на кожу. Не глотать.  
 Держать вдали от пищевых продуктов, напитков и еды.  
**После попадания на кожу промойте водой. После попадания в глаза промойте под проточной водой. Если симптомы сохраняются, обратитесь к врачу.**

**Values:**

<b>REF</b>	Кат - No.:	<b>0209-0102-391</b>	3x 1 мл 2 ммол/л в мк. пробирках, синие 3x 1 мл 7 ммол/л в мк. пробирках, зеленые 3x 1 мл 18 ммол/л в мк. пробирках, красные
<b>LOT</b>	Charge-No.:		Смотри этикетку
	Срок годности до вскрытия		Смотри этикетку
	Температура хранения:		Выбрасывать после достижения срока годности. 2 °C – 8 °C
	Стабильность после вскрытия		8 часов (15 °C – 25 °C)

Значения глюкозы	Границы
2.00 ммол/л 36.0 мг/дл	1.80 – 2.20 ммол/л 32.4 – 39.6 мг/дл
7.00 ммол/л 126.1 мг/дл	6.75 – 7.25 ммол/л L 121.6 – 130.6 mg/dL
18.00 ммол/л 324.1 мг/дл	17.50 – 18.5 ммол/л 315.1 – 333.1 мг/дл

Значения лактата	Границы
2.00 ммол/л 18.0 мг/дл	1.80 – 2.20 ммол/л 16.2 – 19.8 мг/дл
7.00 ммол/л 63.1 мг/дл	6.75 – 7.25 ммол/л 60.8 – 65.3 мг/дл
18.00 ммол/л 162.1 мг/дл	17.50 – 18.5 ммол/л 157.6 – 166.7 мг/дл

## Сенсор Тестовый раствор

### Назначение:

Для In-vitro диагностики

**Сенсор-тестовый раствор** для глюкозы и лактата, готовый к использованию, предназначен для проверки селективности чип-сенсора глюкозы тип I и II, чип-сенсора лактата тип I и II

### Инструкция по применению:

**Сенсор-тестовый раствор** рекомендован для использования на следующих анализаторах: BIOSEN 5130, BIOSEN 5130 AutoCal, BIOSEN 5140, BIOSEN C\_line и BIOSEN S\_line.

Вам необходимо измерять **Сенсор-тестовый раствор** первые три дня с начала использования чип-сенсора и далее дважды в неделю. Результаты измерения должны быть в пределах от 4,8 mmol/L (86 mg/dl Глюкоза, 43 mg/dL Лактат) до 6,4 mmol/L (115 mg/dL Глюкоза, 57 mg/dL Лактат) . В противном случая чип-сенсор должен быть заменен. Этот раствор определяет механические повреждения чип-сенсора.

### Химический состав:

5 mmol/L Глюкозы, 5 mmol/L Лактата, 1 mmol/L Мочевой кислоты и 1 mmol/L Минофен ацита, разведенные в 51 раз в фосфатном буфере с pH 7,2

### Внимание:

Избегать контакта с глазами и кожей. Не глотать. Хранить вдали от пищевых продуктов, напитков и продуктов питания. При попадании на кожу промыть водой. После промыть глаза под струей воды. Если симптомы не проходят, обратитесь к врачу.

### Подробная информация:

<b>h</b>	Реф. №:	<b>5130-6055</b>	Сенсор-тестовый раствор для глюкозы и лактата, готовый к использованию, 20 x 1 mL
<b>g</b>			Смотри упаковку
<b>H</b>	Срок годности закрытых пробирок:		Смотри упаковку
<b>l</b>	Температура хранения:		2 °C - 8 °C

## Sensor Test Solution

76d., 13

### Intended Use:

In-vitro-diagnostics

**Sensor test solution**, glucose and lactate, ready for use, is used to check the selectivity of chip sensor glucose type I and II and chip sensor lactate type I and II.

### Handling Instructions:

**Sensor test solution** is recommended to be used on the following devices: BIOSEN 5130, BIOSEN 5130 AutoCal, BIOSEN 5140, BIOSEN C\_line and BIOSEN S\_line.

You should measure **sensor test solution** daily as a control sample on the first 3 days of sensor use and after that at least twice a week. The results obtained with that solution must be within 4,8 mmol/L (86 mg/dL glucose, 43 mg/dL lactate) and 6,4 mmol/L (115 mg/dL glucose, 57 mg/dL lactate). Otherwise the sensor must be replaced. That solution detects the mechanical integrity of the sensor.

### Chemical Composition:

5.0 mmol/L glucose, 5.0 mmol/L lactate, 1 mmol/L uric acid and 1 mmol/L acetaminophen diluted 51-fold a phosphate buffered solution (pH 7.2) containing further ingredients.

### Warning:

Avoid contact with eyes and skin. Do not swallow.

Keep away from foodstuff, beverages and food.

**After skin contact rinse with water. After eye contact rinse opened eye under running water. If symptoms persist, consult doctor.**

### Details:

<b>h</b>	Item No.:	<b>5130-6055</b>	Sensor test solution, glucose and lactate, ready for use, set of 20 pcs.
<b>g</b>			see label
<b>H</b>	Expiry date unopened tubes:		see label
<b>l</b>	Storage temperature:		2 °C - 8 °C



## Biosen C-Line & Biosen S-Line

Lab accurate glucose and lactate measurement in one test

- ◆ Easy to use
- ◆ Results in 20-45 seconds
- ◆ Up to 120 results an hour
- ◆ Low operating cost

76d. 3

C-LINE	
GP+	• Up to 5 samples
CLINIC	• Up to 20 samples
S-LINE	
LAB+	• Up to 63 samples

<p>Easy to use</p>	<ul style="list-style-type: none"> <li>Multi-lingual touch screen display with step by step instructions</li> <li>Just 20 µl <u>blood, plasma or serum sample</u> required when used with EKF pre-filled 'Safe-Lock' reaction cups (1000 µl)</li> <li>Up to 120 results an hour ← 76d. 6</li> <li>Results in 20-45 seconds</li> <li>Automatically detects presence of reaction cups</li> <li>Chip sensors easily exchangeable, no electrode cleaning required</li> </ul>
<p>Accurate and reliable</p>	<ul style="list-style-type: none"> <li>Enzymatic-amperometric method using chip-sensor technology ← 176d. 1</li> <li>Measuring range: Glucose 0.5–50 mmol/L (9–900 mg/dL); Lactate 0.5–40 mmol/L (5–360 mg/dL) ← 76d. 5</li> <li>Imprecision: CV ≤1.5 % (12 mmol/L) ← 76d. 7</li> <li>Pre-filled 'Safe-Lock' reaction cups eliminate manual dilution</li> <li>Innovative needle and exchanger design eliminates cross contamination</li> <li>3 calibration modes ← 76d. 12</li> </ul>
<p>Maximum efficiency and convenience</p>	<ul style="list-style-type: none"> <li>Dual channel option: Glucose and/or Lactate results from one sample ← 76d. 9</li> <li>Long sensor life: <u>Glucose 60 days/7,500 tests</u>; Lactate 50 days/6,000 tests</li> <li>Sample stable for up to 5 days (refrigeration recommended)</li> <li>STAT position</li> </ul>
<p>Efficient data handling</p>	<ul style="list-style-type: none"> <li>PC, network and printer connectivity via RS232C interfaces</li> <li>Stores up to 1.000 results ← 76d. 20</li> <li>Integrated Barcode reader (optional) ← 76d. 19</li> </ul>

Catalog No.	Name
5213-0051-6200	• Biosen C-Line GP+ (1 measuring channel)
5213-0121-6200	• Biosen C-Line GP+ (2 measuring channels)
5214-0051-2200	• Biosen C-Line Clinic (1 measuring channel)
5214-0121-2200	• Biosen C-Line Clinic (2 measuring channels)
5222-0056-6200	• Biosen S-Line Lab+ (1 measuring channel)
5222-0123-6200	• Biosen S-Line Lab+ (2 measuring channels)



1 Collect 20 µl blood sample in capillary.



2 Place capillary into cup and invert until mixed.



3 Result in 20–45 seconds.

Distributed by

**Manufacturer**  
 EKF-diagnostic GmbH  
 Ebendorfer Chaussee 3  
 39179 Barleben, Germany  
 ☎ +49 (0) 39203 511 0

[www.ekfdiagnostics.com](http://www.ekfdiagnostics.com)

**EKF** | Diagnostics  
 for life

# Biosen

## Glucose & lactate analyzers



### Biosen ordering information

	Analyzers	Reference No.	Contents
Hematology	Biosen C-Line GP+ (1 measuring channel)	5213-0051-6200	1 pack
	Biosen C-Line GP+ (2 measuring channels)	5213-0121-6200	1 pack
	Biosen C-Line Clinic (1 measuring channel)	5214-0051-2200	1 pack
	Biosen C-Line Clinic (2 measuring channels)	5214-0121-2200	1 pack
	Biosen S-Line Lab+ (1 measuring channel)	5222-0056-6200	1 pack
	Biosen S-Line Lab+ (2 measuring channels)	5222-0123-6200	1 pack
Diabetes Care	Consumables	Reference No.	Contents
	Hemolyzing solution cups with 20 end-to-end capillaries	0209-0100-012 (plastic capillaries)	1 set of 1,000 pcs
		0209-0100-014 (plastic capillaries)	5 sets of 200 pcs
	Hemolyzing solution cups with 20 end-to-end capillaries	0209-0100-013 (plastic capillaries)	1 set of 200 pcs
	Hemolyzing solution cups without capillaries	0209-0100-122	1 set of 1,000 pcs
	Hemolyzing solution cups 0.5 mL with 10 end-to-end capillaries	0209-0100-005 (glass capillaries)	1 set of 1,000 pcs
	Capillary holder for end-to-end capillaries	0901-0200-002	1 pc
Capillary holder for end-to-end capillaries	0901-0200-002	1 pc	
Maternal & Women's Health	Sensors	Reference No.	Contents
	Chip sensor glucose (type II)	5206-3011	1 pc
	Chip sensor lactate (type II)	5206-3029	1 pc
	Dummy to insert into sensor-block (type II)	5206-3135	1 pc
Sports Performance	Calibrators & solution	Reference No.	Contents
	Pre-filled multi standard solution	5211-3015	1 set of 50 pcs
		5211-3017	1 set of 100 pcs
	Glucose/Lactate system solution	0201-0002-025	1 bottle of 500 mL
		0201-0002-024	1 bottle of 2,500 mL
0201-0002-026		1 bottle of 5000 mL	
Central Laboratory	Quality control material	Reference No.	Contents
	EasyCon Norm (QC material)	0201-0005-012P6	1 set of 6 pcs
	EasyCon Pat (QC material)	0201-0005-013P6	1 set of 6 pcs
	ReadyCon Norm (test solution)	5130-6152	1 set of 25 pcs
	ReadyCon Pat (test solution)	5130-6162	1 set of 25 pcs
	Sensor test solution	5130-6055	1 set of 20 pcs
Linearity test kit 2-7-18 mmol/L 36-126-324 mg/dL	0209-0102-391	1 set of 3 x 3	
Central Laboratory	Capillaries & sample cup	Reference No.	Contents
	EKF Safecups micro test tubes 2.0 mL	8200-0011-0034	1 set of 1,000 pcs
	Capillaries 20 µL end-to-end, Na-heparized	7111-0011-20H plastic	1,000 pcs (10x100)

76d. 1.2

76d. 1.3

76d. 1.7

76d. 1.1

76d. 1.5

76d. 1.6

ACCESSORIES: PRINTER		PRODUCT CODE	UNIT
	<b>Thermal printer DPU-414</b> with serial and parallel interfaces, power supply (230V/50Hz), printer cable and thermal paper	0620-0105-0334	1 PC

ACCESSORIES: MAINTENANCE PARTS & PERFORMANCE TEST KITS			
	<b>Disinfectant solution</b> , not ready to use	0201-0003-001	1 SET OF 5 PCS
	<b>Cleaning solution, protein remover</b> not ready to use	0201-0004-001	1 SET OF 5 PCS
	<b>Sensor test solution</b> for glucose and lactate, ready to use	5130-6055	1 SET OF 20 PCS
	<b>Linearity test kit</b> glucose / lactate, 2-7-18 mmol/L (36-126-324 mg/dL)	0209-0102-391	1 SET OF 3 X 3 PCS
	<b>200 mL Bottle with lid - empty</b> for BIOSEN C-line as system solution bottle or waste bottle	5211-7119	1 PC
	<b>500 mL Bottle 500 mL with lid - empty</b> for BIOSEN S-line, 5140, 5040 as system solution bottle or waste bottle	0204-0121-050	1 PC
	<b>Pump tube</b> with stopper	5208-1094	1 PC
	<b>Exchanger</b>	5211-1735	1 PC
	<b>Sample canula</b> , for Biosen C-Line	5221-1714-1719	1 PC
	<b>Sample canula</b> , for Biosen S-Line	5221-1714-0521	1 PC
	<b>Service Box</b> , for BIOSEN C-line consisting of: sample canula, pump tube, 2x fuse 250 V/315 mA, hexagon wrensch key, exchanger	5211-7303-0664	1 SET
	<b>Service Box</b> , for BIOSEN S-line consisting of: sample canula, pump tube, 2x fuse 250 V/315 mA, hexagon wrensch key, exchanger	5211-7005-0557	1 SET
	<b>Connector red</b> for the 200 mL bottle for system solution for the Biosen C Line	5211-1383	1 PC
	<b>Connector red</b> for the 500 mL bottle for system solution for the Biosen C Line	5221-1387-0125	1 PC

76d., poz. 1.4

76d., poz.1.9

76d., poz. 1.10

# BIOSEN C\_line, Clinic



## Operator's manual

Analyzer for Glucose and Lactate

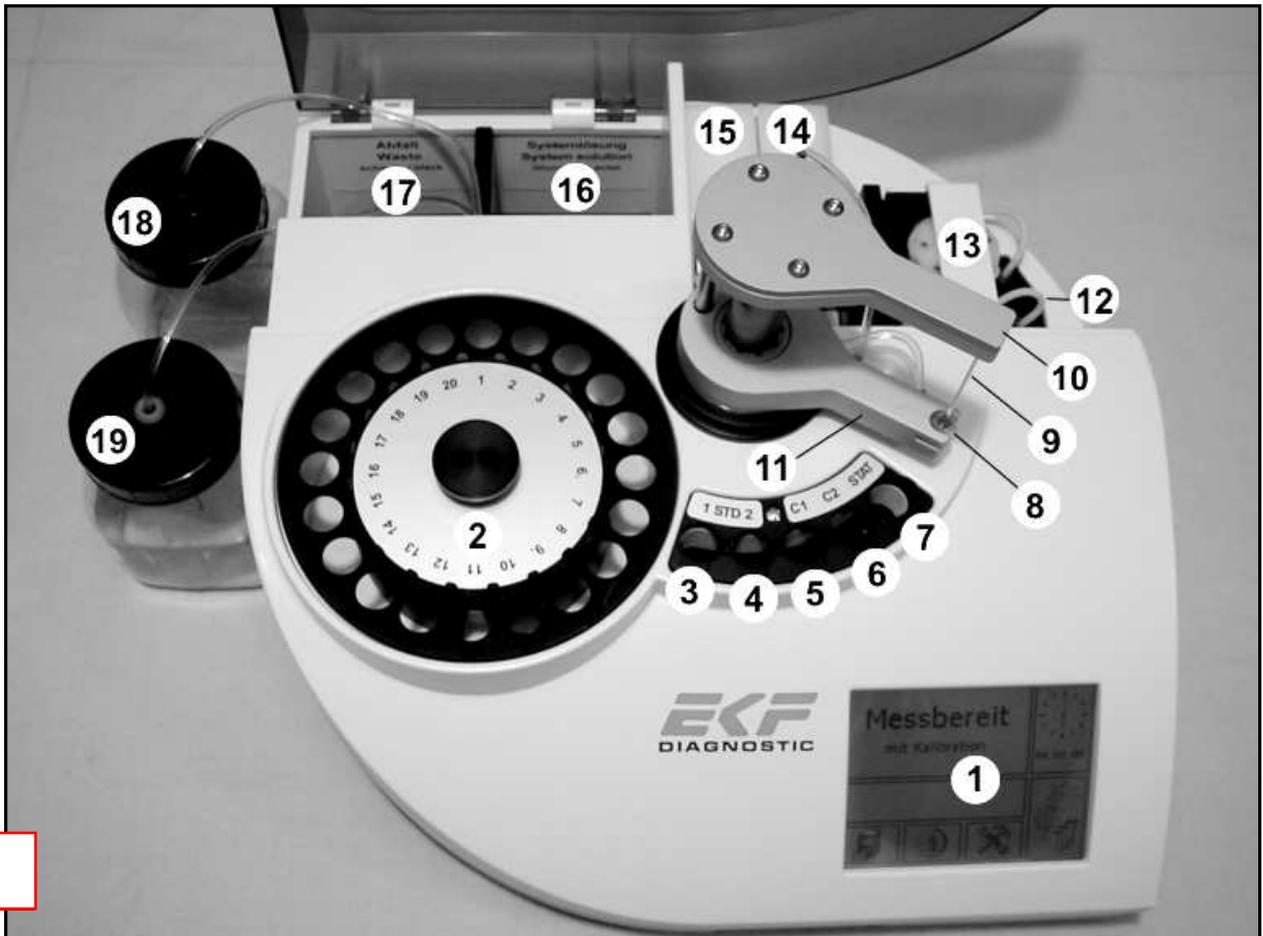
Version 2.0-09/2006  
Subject to technical modifications  
5214-9011-0127

BIOSEN C-LINE

**Demand-oriented  
Glucose/Lactate  
measuring**

### 3. Description of components

Front view:



76d., 4

Figure1

- 1 **Display with Touchpanel**
- 2 **Tray for 20 samples, removable**
- 3,4 **Positions for Standard 1 and 2 (STD1, STD2)**
- 5,6 **Positions for Control 1 and 2 (C1, C2)**
- 7 **Position for STAT**
- 8 **Exchanger (maintenance part)**
- 9 **Sample cannula (maintenance part)**
- 10,11 **Lifter, pivot arm**
- 12 **Tube (maintenance part)**
- 13 **Pump with pump flap**
- 14 **Sensor lid - measuring channel 1**
- 15 **Sensor lid - measuring channel 2**
- 16 **Opening for bottle containing system solution**
- 17 **Opening for waste bottle**
- 18 **Waste bottle with lid, colour code black**
- 19 **Bottle for system solution with lid, colour code red**

---

## 10.3. Device settings

### 10.3.1. Calibration mode

There are 3 calibration modes which can be set:

- **"By starting"**

A calibration takes place first before every measurement. Controls set are measured and evaluated. This also applies to STAT measurements. In the "Ready" window the following is always displayed:

"Ready with calibration"

- **"Periodic"**

The device calibrates itself automatically every 60 min. At measurement start the samples (including STAT) are measured immediately. In the Ready to measure window the following is displayed: "Ready calibration in xx min", where xx stands for the time until the next automatic calibration. If the calibration time runs out while samples are still being measured, the sample measurement is interrupted, calibration is executed and the sample measurement continues (after successful calibration). If a calibration was not successful (e.g. empty standard micro test tube), an error message appears (this needs to be confirmed) and the device changes to the ready to measure state.

The display now shows

"Ready with new calibration".

At measurement start a calibration now takes place.

- **"Time account"**

The device is ready to measure for 60 minutes after a calibration. After measurement start the samples (including STAT) are measured straight away. In the Ready to measure window the following is displayed:

"Ready xx min without calibration".

Once the 60 min have elapsed calibration does not take place automatically. The "Ready" window displays "Ready with calibration". At the next measuring start a calibration takes place again.

### 10.3.2. Sensor selection

This is only possible with a device with two measuring channels and two active sensors.

---

Either one of the two chip sensors installed can be deactivated.  
"Sensor 1" indicates measuring channel 1, and "Sensor 2" indicates measuring channel 2, see also Figure1 – p. 7.

Please note the following:



- The life of a chip sensor is not extended by deactivation.
- A blind sensor, when inserted, deactivates the measuring appropriate channel automatically.
- With measuring channel 2 (sensor 2) deactivated, the measuring time is shortened by approx. 8 seconds.
- With measuring channel 1 (sensor 1) deactivated the measuring time is only shortened by approx. 4 seconds.

### 10.3.3. Units

The unit desired can be selected separately for each measuring channel.

### 10.3.4. Test type

This menu option has no effect at present.

## 10.4. Warning limits

76d., 15

### 10.4.1. Samples

Setting of warning limits for sample measurements, for both measuring channels. The range in which the sample measurements are expected to fall can be entered via the upper and lower limits. If the sample measurements are above or below this limits, a "-" or "+" is displayed next to the value displayed.

The limits which can be set are as follows:

glucose	0,5mmol/l ( 9mg/dl ) – 50mmol/l ( 900mg/dl )
lactate	0,5mmol/l ( 9mg/dl ) – 40mmol/l ( 720mg/dl )

### 10.4.2. Control 1

Here the special position C1 is evaluated, otherwise the procedure is identical to pt.10.4.1. The upper/lower limits must agree with the permitted limits of the control material used.

### 10.4.3. Control 2

Here the special position C2 is evaluated, otherwise the procedure is identical to pt.10.4.1. The upper/lower limits must agree with the permitted limits of the control material used.

---

#### 10.4.4. Breach of limits

These settings control how the device should proceed when set limits have been breached.

- **"Controls – continue measurement?"**

If set limits have been breached in Control 1 (C1) or Control 2 (C2), measurement of the samples (tray) can be aborted or continued.

- **"Samples – double determination?"**

If set limits have been breached during sample measurement, a second measurement of this sample can be carried out (double check).

76d., 17

#### 10.5. Date / Time

Date and time settings.

#### 10.6. Selecting printer type

At present the serial DPU 414 printer is available.

#### 10.7. EDP

This menu option contains all relevant parameters for connecting the device with the hospital computers. Changes should only be made by informed personnel.

##### 10.7.1. Transfer protocol

Here the structure of the transfer protocol can be set. At present the "**BIOSEN**" protocol is supported. For protocol structure see also pt. 11.2.2 – p. 35.

##### 10.7.2. Transmission parameters

Adjustable Baud rates and parameters (length, start/stop, parity)

Possible Baud rates: 1200, 2400, 4800, 9600

Possible parameters:	8, 1, Even	7, 1, Even	7, 2, Even
	8, 1, Odd	7, 1, Odd	7, 2, Odd
	8, 1, No	7, 1, No	7, 2, No

## 15. Technical data

Measurement principle	Enzymatic/ amperometric
Electrode	Chip sensor
Measurement range	<u>glucose</u> : 0.5-50 mmol/L (9-900 mg/dL) <u>lactate</u> : 0.5-40 mmol/L (5-360 mg/dL)
Accuracy	CV ≤ 1.5% at 12 mmol/L 
Stability (drift)	≤ 3% over 10 tests, based on 12 mmol/L 
Lifetime of the sensor (on average)	<u>glucose</u> : 60 days or 7500 tests <u>lactate</u> : 50 days or 6000 tests
Sample material	Blood, plasma or serum
Sample volume	20 µL (10 µL)
Reaction vessels	1.5 ML or 2.0 ML micro test tubes
Ambient temperature during operation	+15 to +35 °C
Storage temperature	<u>device</u> : -20°C to + 50°C <u>glucose sensor</u> : +4°C to +8°C (fridge) <u>lactate sensor</u> : -18°C (deep freezer)
Relative Air humidity	20 – 85 %
Mains power	100 – 230 VAC / 50 – 60 Hz
Power consumption	≤ 20 VA (according to specification)
Dimensions (LxWxH)	280 x 280 x 95 mm
Weight	approx. 3 - 5 kg (according to specification)
EDP	RS 232C (V.24) interface
Printer	Parallel interface, RS 232 C (V.24)
Display / keyboard	Graphic touchpanel (320 x 240 Pixels) 
Memory	500 readings with position, date and time
Languages	German, English, Russian, other languages on request