Performance evaluation of MiniCollect® Safety Lancets and MiniCollect® Lancelino Safety Lancet

Background:

The manufacturer Greiner Bio-One offers various types of automated safety lancets that differ according to:

• Shape of the blade (needle / blade)
• Activation mode (by pressing the button /contact-activated)
• Penetration depth

The MiniCollect® Lancelino Safety Lancets and MiniCollect® Safety Lancets are designed for use in the daily capillary blood collection routine when delegated by a qualified practitioner. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with the instructions.

The selection of safety lancet must be done based on skin thickness of the patient (age) and required volume of blood sample (depending on tests to be performed from the capillary blood sample).

Study Objective:

The aim of this study was to demonstrate

- suitability of different safety lancets (considering depth of penetration, blade type and activation mode) for collecting 500 µl of capillary blood
- the volume of sampled capillary blood for each of specified lancet type
- the number / percentage of unsuccessful blood sampling in relation to
  a) default volume of blood and
  b) average blood volume for each type of lancet declared in this study
- degree of pain for each type of lancet based on the number of respondents (only those who were able to define it: age group > 6 years). Score from 1-3 in according of universal scale for pain relief: 1- Painless / can be ignored, 2- Moderate pain / Acceptable, 3 Very painful
- rating for each type of lancet by medical staff evaluating the score of 1-5 (1- excellent, 2- very good, 3- good, 4 acceptable and 5 bad) according to next criteria
  a) Evaluate characteristics of lancets - the force necessary for preparation the lancet prior to sampling and the force required for sampling as well as audible and / or visual sign that activation has been made.
  b) Define subjective assessment of medical staff sampling capillary blood on basis of their own experience and take the following criteria into account: ease of handling (size, hand position, sense of safety in selection of the puncture site), activation method and successful blood sampling in the first attempt.

Study design and procedure:

Types of lancets evaluated in this study:

Item	Description	Needle/Blade	Dept [mm]
450428	MiniCollect® Safety Lancet (green)	1.5 mm (Blade)	1.5
450429	MiniCollect® Safety Lancet (blue)	1.5 mm (Blade)	2.0
450522	MiniCollect® Lancelino Safety Lancet (blue)	21G (needle)	1.8

The applied blood sampling procedure was in accordance with National Recommendations for Capillary Sampling (1,2) and manufacturer recommendations for capillary blood draw (Greiner Bio-One). The arterialization or warming of puncture site (hand/finger) was performed if capillary blood sample was used for blood gas analysis or when the puncture area was cold or circulation was poor. The

arterialization procedure was done by covering the puncture site 3-5 min prior to puncture with a lukewarm tap water or warm moist towel at a temperature of 42 °C or less.
Handling with MiniCollect® Safety Lancets was performed according to the manufacturer's recommendation:
After selecting MiniCollect® Safety Lancet activated by pressing the button (see Materials for capillary blood sampling, items 1 and 2), the lancet was firmly held and the lancet cap was removed by rotation movement. Then, the palm was firmly held to keep the puncture site stable. The lancet was positioned above the puncture site, pressed against the skin and the lancet was activated by pressing the button. For MiniCollect® Lancelino Safety Lancets (see Materials for capillary blood sampling, Item 3), the palm was held with the hand firmly to prevent sudden movements. The lancet was lightly pressed against the puncture site until the lancet was activated.
Immediately after the prick, the lancet was removed with an upward movement and disposed of into an appropriate container for sharp infectious waste (4-10).
After the site puncture, the first drop was wiped and discarded of (unless otherwise recommended – e.g. some manufacturers of glucose meters require the first drop of blood). Gentle intermittent pressure was applied on surrounding tissue for a second drop of blood and when the tip of the microtube touched the drop, blood flowed into the microtube by capillary action or gravity-flow principle, depending on the type of microtube. Repeated strong pressure which can lead to hemolysis or tissue fluid contamination of the sample, is not allowed. (1,2,3)

Note: The final point of blood sampling in this study was defined as follows: when light pressure on the surrounding tissue was not enough to form a blood droplet collected in a predetermined microtube without touching the skin (see: Materials for capillary blood sampling, Item 4. and Item 5).
Blood was sampled exclusively by trained lab staff (laboratory technicians: senior and trainees, laboratory diagnostics bachelors: senior and trainees, medical biochemistry and laboratory medicine engineer: senior and trainee, as well as specialist in medical biochemistry and laboratory medicine).

Study participants:

Group 1. Donors/Volunteers: adults, agreed to sampling capillary blood at the same time with all three (1-3) specified lancets to defined final sampling point with each lancet. Every puncture was done on another finger (middle finger and ring finger of both arms were used). Planned number of study participants was minimum of 60 donors/volunteers.

Group 2. All patients at 1-18 years of age who had a request for Complete Blood Count (CBC) (Green Lancet), CBC and Blood Gas and Acid-base Balance (ABS) (Blue Lancet) or Bleeding Time (Lancelino Blue lancet) from capillary blood. Each sampling was running to defined endpoint. Hospital patient and outpatient who are in the phase of acute or chronic illnesses or healthy patient (before the control or systematic examination or as part of pre-operative or diagnostic treatment) were included in the study. This way, all healthy and non-healthy patients were covered. A large participant number in this group could provide reliable data of capillary blood volume that could be sampled with a certain type of lancet. Minimal planned number of study participants in this group for each type of lancet was 60.

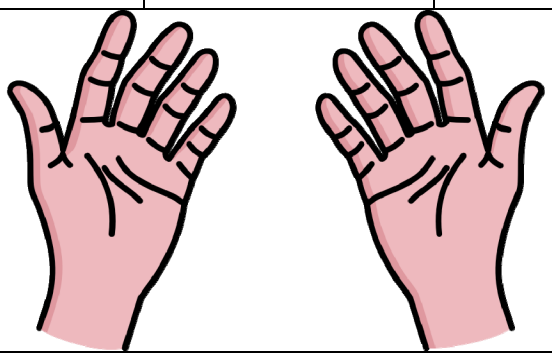
Assessment of study results was done in view of:

Specific parameters:

a) Volume (µL) of capillary blood sample (average volume, median with confidence interval (95% CI) and range from minimum and maximum blood volume in total of participants for each group and lancet type).
   Comparison of volume in both groups was also performed. For statistical data processing MedCalc Software Version 18.11.3 was used.
b) Definition of pain (in the group of donors/volunteers and in the group of children who could define the pain): rating from 1 to 3
c) Lancets rating (medical staff) from 1 to 5

Assessment Sheet:

Date / Donor number: ……/……

Product - **Lancet which is used** for the blood collection	450428 MiniCollect Safety Lancet	450429 MiniCollect Safety Lancet	450522 Lancelino Safety Lancet
Indicate the lancet used (X)			
Volume of collected blood (µl)			
Indicate the finger used (X)			

Evaluation of pain degree was defined at the end of the study according to level score from 1 to 3 for each type of lancet in both groups of participants according to the scheme:

Degree of pain level	 Painless / can be ignored	 Moderate pain /acceptable	 Very painful
Mark participants appropriate answer (X)			

The rating of each type of lancet by medical staff of afore mentioned lancets was used and rated by grades 1-5 according to the scheme:

Lancet Raiting	1 excellent	2 very good	3 good	4 acceptable	5 bad
Mark appropriate answer of laboratory staff (X) (see: Study Objectives, Item 5)					

Results:

Table 1 (Annex) summarizes the measured blood volume (µL) in **Group 1** of participants for all three types of MiniCollect® Safety Lancets by Greiner Bio-One and score of pain (1-3).

Table 2 (Annex) represents the measured blood volume (µL) in **Group 2** of participants for MiniCollect® Safety Lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and rating pain (1-3).

Table 3 (Annex) shows the measured blood volume (µL) in **Group 2** of participants for MiniCollect® Safety Lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and rating pain (1-3)

Table 4 (Annex) indicates the measured blood volume (µL) in **Group 2** of participants for MiniCollect® Lancelino Safety Lancets, Item 450522 (21G, penetration depth 1.8 mm, blue) and rating pain (1-3)

Figure 1-3 show the volume of capillary blood in **Group 1** after use of:

- MiniCollect® Safety Lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green)

- MiniCollect® Safety Lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue)
- MiniCollect® Lancelino Safety Lancet Item 450522 (21G, penetration depth 1.8mm, blue)

Figure 4 -6 indicate the volume of capillary blood in **Group 2** after use of:

- MiniCollect® Safety Lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green)
- MiniCollect® Safety Lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue)
- MiniCollect® Lancelino Safety Lancet Item 450522 (21G, penetration depth 1.8 mm, blue)

Comparison of blood volume between different types of Greiner Bio-One automated safety lancets and between different investigated groups

Statistically significant difference in the volume of blood was detected with MiniCollect® automated safety lancets number 450428 (penetration depth1.5 mm, blade width 1.5 mm, green), meaning that this lancet achieves significantly higher blood volume in adults (**Group 1**) than in children (**Group 2**). (**Figure 7**)

Figure 8 presents statistically significant difference in volume of blood sampled by MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm; blue), which means that this lancet achieves a significantly higher blood volume in adults (**Group 1**) than in children (**Group 2**).

In **Figure 9,** the graph presents that there was no statistically significant difference in the volume of blood sampled with MiniCollect Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) meaning that this lancet achieves equal volume of blood in adult (**Group 1**) and children (**Group 2**), respectively or independently of the patient age.

Investigated difference in sampled blood volume between different types of lancet and within the same group of participants.

Figure 10 MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) in adults (**Group 1**) presented statistically significant differences in the volume of sampled blood.

Figure 11 MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) in children (**Group 2**) did not present statistically significant differences in the volume of sampled blood.

Figure 12 MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in adults (**Group 1**) presented statistically significant differences in the volume of sampled blood.

Figure 13 MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in adult population (**Group 1**) showed statistically significant differences in the volume of sampled blood.

Figure 14 MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in children's population (**Group 2**) showed statistically significant differences in the volume of sampled blood.

Figure 15 MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in children's population (**Group 2**) showed statistically significant differences in the volume of sampled blood.

ASSESSMENT OF PAIN DEGREE IN BOTH INVESTIGATION GROUPS

Figure 16 MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) in adult population (**Group 1**) were estimated for pain degree by average level 1: painless / can be ignored.

Figure 17 MiniCollect® automated safety lancets Item 450428 (penetration depth 2 mm, blade width 1.5 mm, green) in children's population (**Group 2**) were estimated for pain degree by average level 1: painless / can be ignored.

Figure 18 MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) in adult population (**Group 1**) were estimated for pain degree by average level 1: painless / can be ignored.

Figure 19 MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) in children's population (**Group 2**) were estimated for pain degree by average level 2: moderate pain / acceptability.

Figure 20 MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in adult population (**Group 1**) were estimated for pain degree by average level 1: painless / can be ignored (by median) and 2: moderate pain / acceptable (by mean value).

Figure 21 MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in children's population (**Group 2**) were estimated for pain degree by average level 1: painless / can be ignored.

Figure 22 MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue), estimated for pain degree by average level of adult population (**Group 1**) and children's population (**Group 2**) were statistically significant.

Figure 23 MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green), estimated for pain degree by average level of adult population (**Group 1**) and children's population (**Group 2**) showed statistically significant differences.

Figure 24 MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue), estimated for pain degree by average level of adult population (**Group 1**) and children's population (**Group 2**) did not show statistically significant differences.

Figure 25. MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) showed statistically significant differences in assessment for pain degree by adult population (**Group 1**).

Figure 26. MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) showed a statistically significant difference in the assessment of the pain by adult population (**Group 1**).

Figure 27. MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) showed statistically significant differences in the assessment of the pain by adult population (**Group 1**).

Figure 28. MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue), showed statistically significant differences in assessment of the pain by children's population (**Group 2**).

Figure 29. MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) did not show statistically significant differences in assessment of pain by children's population (**Group 2**).

Figure 30. MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) did not show statistically significant differences in assessment of pain by children's population (**Group 2**).

EVALUATION OF LANCETS ASSESSMENT BY MEDICAL PERSONAL (ACCORDING TO PROFESSIONAL DEGREE)

All blood samplers in this study unanimously assessed the lancets MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) with score 1 - excellent, while Lancelino's automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8mm, blue) with score 2 - very good. The lower assessment for Lancelino lancets is probably due to experience and convenience. The samplers' explanation is: This lancet is contact-activated model and samplers have less control over the moment of activation. Also, the reason of less assessment is due to children's population that is restless and more difficult to control during activation, random skin contact is possibly resulting in an uncontrolled puncture.

Conclusion:

Comparison of blood volume obtained by sampling of various types of Greiner Bio-One automated safety lancets in both groups (Group 1: Adults > 18 years, Group 2: Children <18 years) showed that

1. Mean blood volume levels were significantly different in two examined participants for MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) (see Figure 7 and Figure 8), while automated contact-activated lancets Lancelino Item 450522 (21G, penetration depth 1.8 mm, blue) do not have statistically significant differences in obtained blood volume for Group 1 and Group 2 (Figure 9).

   That means depending on the age of the population, different volumes are achieved by using the same capillary blood sampling lancets (green, blue). At the same time, contact-activated lancets (Lancelino, blue) is independent of participant's age compared to obtained blood volume.

2. Statistically significant differences were present in sampled blood volume for all examined groups and lancets except in children where approximately the same blood volume could be sampled with MiniCollect® automated safety lancet Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) (Figures 10 -15).

This study has highlighted the importance of selecting the type of lancet that will be used in accordance to patient age and with regard to the volume of blood that is needed to be achieved.

3. Considering above conclusions (points 1 and 2), blood volumes for each lancet in both populations (children, adults) are defined as follows:

	450428 - green			**450429 - blue**			**450522 - Lancelino - blue**		
	Arithmetics mean of blood volume (µL)	Median (µL)	Range (µL)	Arithmetics mean of blood volume (µL)	Median (µL)	Range (µL)	Arithmetics mean of blood volume (µL)	Median (µL)	Range (µL)
Adult (>18 years) (Group 1)	**401,8** (95%CI: 370,3 - 433,2)	**500** (95%CI: **438,5 - 500,0**)	120 to >500	**454,2** (95%CI: 434,2 - 474,2)	**500** (95%CI: **500,0 - 500,0**)	250 to >500	**145,6** (95%CI: 116,98 - 174,28)	**100** (95%CI: **70,0 - 150,0**)	20 - 500
Children (<18 years) (Group 2)	**353,0** (95% CI: 333,6 - 372,4)	**350** (95% CI: **300,0 - 400,0**)	150 - 500	**364,4** (95%CI: 344,6 - 384,2)	**335** (95% CI: **320,0 - 400,0**)	120 - 500	**136,3** (95% CI: 104,1 - 168,6)	**70** (95% CI: **60,0 - 150,0**)	20 - 500

4. The evaluation of the pain assessment according to age and lancet types showed a statistically significant difference (Figures 22-30)

5. Lancets rating by medical lab staff with different professional qualifications was unanimous for all types of lancets and was rated 1 - excellent for MiniCollect® automated safety lancets Item 450429 (blue) and Item 450428 (green) and 2 - Very good for automated contact-activated safety lancets Lancelino Item 450522 (Blue):

6. The assessment of the pain by respondent is subjective since it is particularly difficult for children to define because it involves fear of blood sampling and in adult population after the third puncture it is no longer possible to achieve an objective evaluation, as well as medical staff based on experience and habits. For this reason, these assessments should be interpreted in this way

References:

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Annex:

Table 1. Measured blood volume (µL) in **Group 1** of participants for all three types of MiniCollect® Safety Lancets and score of pain (1-3) with statistical data.

			Type of MiniCollect® Safety Lancets by Greiner Bio-One (Item/label)						
			450428-green		450429 - blue		450522 - Lancelino - blue		note
Number	gender	age (year)	Volume (µL)	Pain (1-3)	Volume (µL)	Pain (1-3)	Volume (µL)	Pain (1-3)	
1	F	35	450	1	>500	1	130	2	
2	F	54	480	2	>500	1	500	1	
3	M	46	>500	1	>500	1	150	2	
4	M	39	250	2	500	1	130	2	
5	F	24	250	2	500	1	350	1	
6	F	26	130	2	250	2	70	3	After arterialization
7	M	20	120	2	350	1	70	2	After arterialization
8	M	29	>500	1	>500	1	50	2	
9	F	25	150	1	400	1	50	3	
10	F	33	200	2	400	1	250	1	
11	F	19	200	2	>500	1	60	3	
12	F	60	500	1	>500	1	50	2	
13	F	36	>500	1	>500	1	200	1	
14	F	36	>500	1	>500	1	150	1	After arterialization
15	F	52	500	1	500	1	50	3	After arterialization
16	F	42	500	1	>500	1	20	2	After arterialization
17	F	23	500	1	>500	1	200	1	
18	F	50	500	1	>500	1	70	3	After arterialization
19	F	30	400	1	300	1	70	2	After arterialization
20	F	41	300	1	250	1	500	1	
21	F	22	200	1	>500	1	70	2	
22	F	62	500	1	>500	1	50	2	

23	M	45	>500	1	500	1	200	1	
24	M	44	>500	1	>500	1	150	1	
25	F	28	500	1	500	1	70	2	
26	F	40	500	1	500	1	50	2	
27	M	40	500	1	>500	1	200	1	
28	F	50	500	1	>500	1	100	2	
29	F	42	400	1	300	1	70	2	
30	F	45	300	1	400	1	200	1	
31	F	35	450	1	>500	1	130	1	
32	F	55	500	1	>500	1	500	1	
33	M	46	>500	1	>500	1	150	1	
34	M	39	250	2	500	1	130	1	
35	F	24	250	2	500	1	350	1	
36	F	26	130	1	250	2	70	3	
37	M	20	120	2	350	1	70	2	After arterialization
38	M	29	>500	1	>500	1	70	2	After arterialization
39	F	25	150	3	400	1	50	2	
40	F	33	200	1	400	1	250	1	
41	F	19	200	2	>500	1	70	1	
42	F	60	500	1	>500	1	50	2	
43	F	36	>500	1	>500	1	200	1	
44	F	36	>500	1	>500	1	150	1	
45	F	52	500	1	500	1	100	1	
46	F	42	500	1	>500	1	50	2	
47	F	23	500	1	>500	1	200	1	
48	F	50	500	1	>500	1	50	3	
49	F	30	400	1	300	1	70	2	
50	F	41	300	1	250	1	500	1	

51	F	22	200	1	>500	1	70	1	
52	F	62	500	1	>500	1	50	2	
53	M	45	>500	1	500	1	200	1	
54	M	44	>500	1	>500	1	150	1	
55	F	28	500	1	500	1	50	2	
56	F	40	500	1	500	1	70	1	
57	M	40	500	1	>500	1	200	1	
58	F	50	500	1	>500	1	70	2	
59	F	42	400	1	300	1	70	1	
60	F	44	300	1	250	1	200	1	
61	M	44	>500	1	>500	1	150	1	
62	F	28	500	1	500	1	70	2	
63	F	40	500	1	500	1	50	2	After arterialization
64	M	40	500	1	>500	1	200	1	
65	F	50	500	1	>500	1	70	1	After arterialization
66	F	42	400	1	300	1	70	1	After arterialization
67	F	44	300	1	300	1	200	1	
68	F	35	450	1	>500	1	130	1	
69	F	55	450	1	>500	1	500	1	
70	M	46	>500	1	>500	1	150	1	
71	M	39	250	1	500	1	130	1	
Arithmetic mean of volume (µL)/rating pain		38,5	401,8	1,18	454,2	1,02	145,6	1,55	
median		40	500	1	500	1	100	1	
min-max		19 -62	120 to >500	1-3	250 do >500	1-3	20 - 500	1-3	
Standard deviation (SD)			132,9	0,42	84,4	0,17	121,0	0,67	
95% confidence interval (95%CI) for the arithmetic mean			370,3 to 433,2	1,1 to 1,3	434,2 to 474,2	0,98 to 1,07	116,98 to 174,28	1,4 to 1,7	

95% confidence interval (95%CI) for the median	438,5 to 500,0	1,0 to 1,0	500,0 to 500,0	1,0 to 1,0	70,0 to 150,0	1,0 to 2,0	
Number and percentage of cases when blood volume was 500 µL from first attempt	39/71 (54,9%)	-	53/71 (74,6%)	-	4/71 (5,6%)	-	
Number and percentage of cases when blood volume was >500 µL from first attempt	14/71 (19,7%)	-	38/71 (53,5%)	-	0/71 (0%)	-	
Number and percentage of cases unsuccessful attempts at blood sampling (two punctuations needed)	0	-	0	-	0	-	

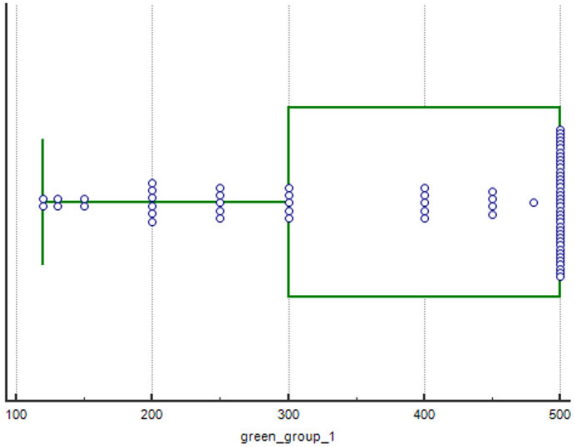

Figure 1 Volume distribution (µL) of capillary blood in **Group 1** after MiniCollect® Safety Lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) were used.

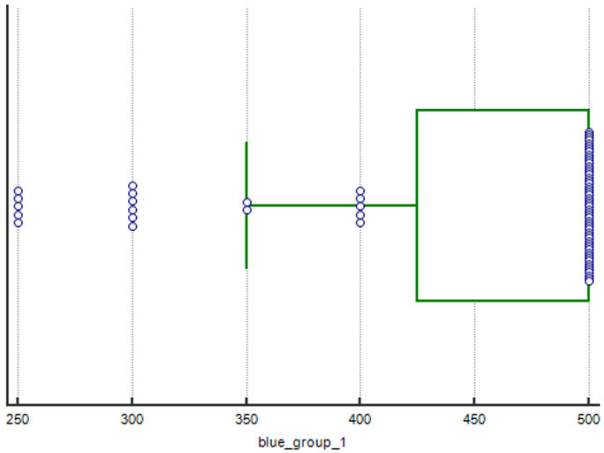

Figure 2 Volume distribution (µL) of capillary blood in **Group 1** after MiniCollect® Safety Lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, **blue**) were used.

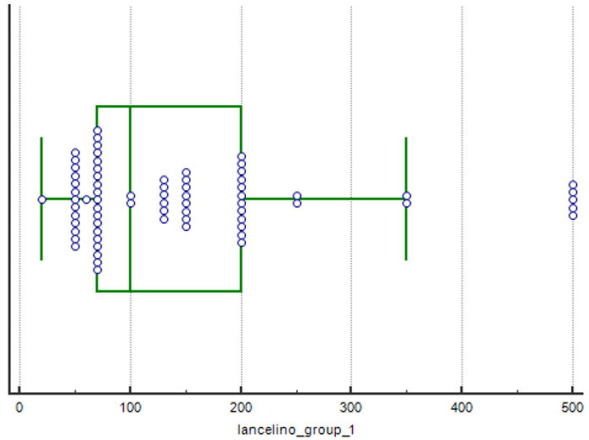

Figure 3 Volume distribution (µL) of capillary blood in **Group 1** after MiniCollect® **Lancelino** Safety Lancet Item 450522 (21G, penetration depth 1.8mm, blue) were used.

Table 2. Measured blood volume (µL) in **Group 2** of participants for MiniCollect® Safety Lancets Item 450428 (penetration depth1.5 mm, blade width1.5 mm, green) and rating pain (1-3) with statistical data. In this group, number of participants was 100.

No.	No. Tube	Participant ID	Volume (µL)	Rating Pain (1-3)	Note
1.	23	137	250		
2.	38	123	600	1	
3.	39	65	350	1	
4.	40	85	450		
5.	42	100	400		
6.	20	152	240	2	
7.	22	177	300		
8.	24	164	300		
9.	35	220	300		
10.	18	127	250	1	
11.	25	14	250	2	arteriolization
12.	8	56	300		
13.	9	83	180		
14.	13	87	200	1	
15.	15	88	300	3	
16.	18	99	200		
17.	19	132	180		
18.	20	138	400	2	
19.	21	137	400		
20.	23	147	250		
21.	25	139	450		
22.	28	160	320		
23	31	185	400		
24.	32	186	350		

25.	1	10	600	1	
26.	15	71	300		
27.	16	72	300		
28.	22	132	500	3	
29.	29	156	300	1	
30.	31	124	300	2	
31.	19	5	500	1	
32.	22	142	500	1	
33.	26	154	400	2	
34.	7	74	300	1	
35.	8	72	600	1	
36.	12	12	400		
37.	13	96	500		
38.	25	132	350		
39.	6	5	500		
40.	20	138	400		
41.	12	53	500		
42.	16	113	500	1	
43.	20	121	200	1	
44.	21	125	300	1	
45.	15	134	250	2	
46.	23	112	250	3	
47.	31	142	300		
48.	9	94	300	1	
49.	11	131	400		
50.	15	4	600	1	
51.	10	98	500	1	
52.	15	134	350	1	

53.	18	142	450		
54.	13	131	300	1	
55.	27	131	300	1	
56.	29	132	600	1	
57.	30	134	300	1	
58.	7	107	500	3	
59.	8	110	600	2	
60.	3	148	300	1	
61.	4	157	200		
62.	7	179	280		
63.	7	35	300	1	
64.	11	62	400	3	
65.	21	131	400	1	
66.	3	16	300	3	
67.	4	46	300	1	
68.	7	76	250		
69.	21	168	200	2	
70.	24	15	300	1	
71.	27	154	350	1	
72.	17	82	350	1	
73.	19	97	400	1	
74.	10	56	450	1	
75.	11	54	400	3	
76.	23	184	400	1	
77.	30	216	350	2	
78.	31	219	500	1	
79.	2	48	300		
80.	12	57	450		

81.	13	61	400	1	
82.	21	77	300	2	
83.	17	124	400	1	
84.	23	8	200		
85.	21	129	250	1	
86.	13	84	300	1	
87.	18	107	500	1	
88.	19	111	400		
89.	25	124	400	1	
90.	8	156	250	1	
91.	13	167	450		
92.	14	168	350	1	
93.	17	171	450	1	
94.	19	46	500	3	
95.	6	101	150	1	
96.	9	22	350	1	
97.	14	122	200	1	
98.	24	97	300	1	
99.	35	153	250	1	
100.	65	100	300	1	
Arithmetic mean of volume (µL)/rating pain			353,0	1,4	
median			350,0	1,0	
min-max			150 -500	1-3	
Standard deviation (SD)			97,8	0,72	
95% confidence interval (95%CI) for the arithmetic mean			333,6 to 372,4	1,2 to 1,6	
95% confidence interval (95%CI) for			300,0 to	1,0 to 1,0	

the median	400,0		
Number and percentage of cases when blood volume was 500 µL from first attempt	23/100 (23%)	-	
Number and percentage of cases unsuccessful attempts at blood sampling (two punctuation needed)	0%	-	

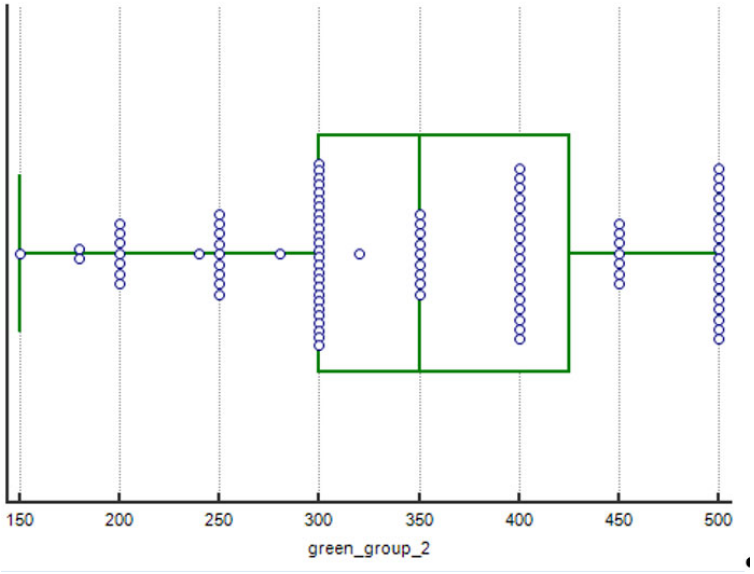

Figure 4 Volume distribution (µL) distribution of capillary blood in **Group 2** after MiniCollect® Safety Lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) were used.

Table 3. Measured blood volume (µL) in **Group 2** of participants for MiniCollect® Safety Lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) and rating pain (1-3) with statistical data. Number of participants in this group was 108.

No.	No. Tube	Participant ID	Volume (µL)	Rating Pain (1-3)	Note
1.	13	66	320		
2.	14	57	320	1	
3.	15	48	250	1	
4.	16	57	600		
5.	17	67	320		
6.	18	78	320	1	
7.	19	121	500	1	
8.	20	108	550		
9.	21	123	600		
10.	22	132	250	2	
11.	24	20	300	3	
12.	25	93	250		
13.	27	74	400	1	
14.	28	151	320		
15.	29	147	400		
16.	30	154	500		
17.	31	30	400		
18.	32	114	320	2	
19.	33	116	550	1	
20.	34	162	600		
21.	35	169	300		
22.	36	184	270	3	
23.	37	187	200		
24.	41	181	520	1	

25.	43	191	370	2	
26.	44	195	550		
27.	20	124	270		
28.	21	150	300		
29.	28	188	300		
30.	29	193	440		
31.	30	189	350		
32.	31	232	650	1	
33.	32	223	320	1	
34.	33	225	420	2	
35.	34	233	600	1	
36.	35	180	470	1	
37.	36	147	520		
38.	37	139	570	1	
39.	38	236	920	1	
40.	40	252	320	2	
41.	41	254	400		
42.	42	259	620	1	
43.	43	257	250		
44.	44	261	230		
45.	19	135	300	2	
46.	22	152	300	2	
47.	24	169	300		
48.	25	166	350		
49.	27	171	200		
50.	28	172	320		
51.	32	195	280	2	
52.	13	111	200		

53.	15	143	550		
54.	18	160	120	3	
55.	19	165	230		
56.	21	151	400		
57.	26	184	570		
58.	27	112	250		
59.	28	176	400	1	
60.	29	13	310		
61.	31	198	270	2	
62.	32	203	450		
63.	34	213	310		
64.	36	219	570		
65.	37	225	300		
66.	38	224	550		
67.	19	124	600	1	
68.	20	61	450	1	
69.	21	122	570	1	
70.	22	149	420	1	
71.	23	148	500	2	
72.	24	163	300	2	
73.	26	162	680	1	
74.	27	141	300		
75.	28	176	570		
76.	29	187	200	3	
77.	30	194	250	3	
78.	31	186	200	3	
79.	36	197	420		
80.	37	195	600		

81.	38	201	300		
82.	39	204	310		
83.	41	216	500	1	
84.	43	222	580	1	
85.	19	8	320	2	
86.	20	155	350	2	
87.	21	172	280	2	
88.	22	141	420		
89.	23	181	300	2	
90.	24	185	300	2	
91.	25	195	270		
92.	26	152	370		
93.	27	190	520	1	
94.	28	202	550	1	
95.	29	231	200	3	
96.	31	237	420		
97.	32	244	250		
98.	2	70	280		
99.	3	71	400	2	
100.	10	92	420		
101.	14	78	200		
102.	22	145	200		
103.	24	116	280	3	
104.	26	134	320	2	
105.	29	161	350	2	
106.	13	66	300	2	
107.	17	99	400	1	
108.	23	131	400	1	

Arithmetic mean of volume (µL)/rating pain	364,4	1,67	
median	335	2	
min-max	120 -500	1-3	
Standard deviation (SD)	103,8	0,72	
95% confidence interval (95%CI) for the arithmetic mean	344,6 to 384,2	1,47 to 1,87	
95% confidence interval (95%CI) for the median	320,0 to 400,0	1,0 to 2,0	
Number and percentage of cases when blood volume was 500 µL from first attempt	30/108 (27,8%)	-	
Number and percentage of cases unsuccessful attempts at blood sampling (two punctuation needed)	0%	-	

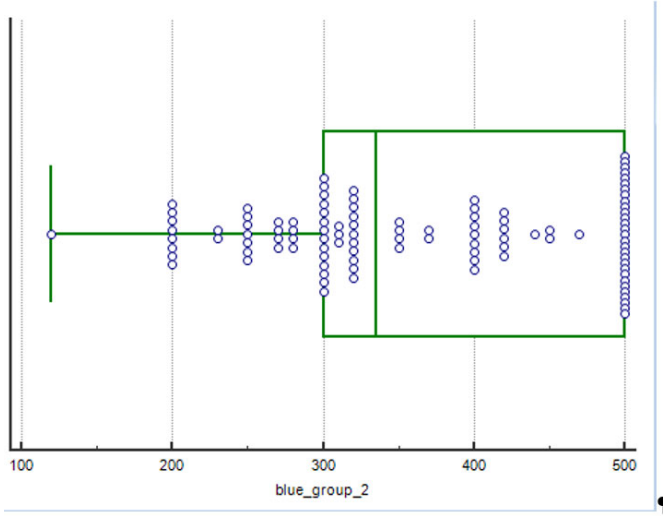

Figure 5 Volume distribution (µL) distribution of capillary blood in **Group** 2 after MiniCollect® Safety Lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, **blue**) were used.

Table 4. Measured blood volume (µL) in children's population (**Group 2)** of participants for MiniCollect® Lancelino Safety Lancets, Item 450522 (21G, penetration depth 1.8mm, blue) and rating pain (1-3) with statistical data. Number of participants in this group was 60.

No.	No. Tube	Participant ID	Volume (µL)	Rating Pain	No.
1	10	56	60		After arterialization
2	11	54	70		After arterialization
3	23	184	50		
4	30	216	50		
5	31	219	250		
6	21	168	130	1	
7	24	15	500	3	
8	27	154	150		
9	17	82	130		
10	19	97	350	2	
11	17	124	50	3	After arterialization
12	23	8	20	1	After arterialization
13	21	129	200	2	
14	13	84	50	1	After arterialization
15	18	107	70	1	After arterialization
16	2	48	60		
17	12	57	50	1	
18	13	61	200		
19	21	77	150		After arterialization
20	25	124	60	1	
21	20	155	200		
22	21	172	50		

23	22	141	70	1	
24	23	181	200	1	
25	17	171	50		
26	18	46	20		
27	19	111	500	2	
28	8	156	50	1	
29	13	167	200		
30	14	168	150		
31	24	185	130	1	
32	25	195	500	1	
33	26	152	150	3	
34	27	190	130		
35	28	202	350	1	
36	29	231	60		
37	31	237	70	1	After arterialization
38	32	244	50	1	After arterialization
39	2	70	50	1	
40	3	71	250		
41	10	92	60	1	
42.	14	78	50	1	
43.	22	145	200	1	
44.	24	116	150	1	
45.	26	134	50	3	
46.	29	161	20	2	
47.	13	66	200		
48.	20	155	50		
49.	21	172	70	3	
50.	22	141	500		

51.	13	66	60	1	
52.	14	57	50		
53.	15	48	200	1	
54.	16	57	150	1	
55.	17	67	50	1	
56.	18	78	20		
57.	19	121	200	1	
58.	20	108	50	1	
59.	21	123	70	1	
60.	22	132	100	1	
Arithmetic mean of volume (µL)/rating pain			136,3	1,39	
median			70	1,0	
min-max			20 -500	1-3	
Standard deviation (SD)			124,9	0,73	
95% confidence interval (95%CI) for the arithmetic mean			104,1 to 168,6	1,1 to 1,6	
95% confidence interval (95%CI) for the median			60,0 to 150,0	1,0 to 1,0	
Number and percentage of cases when blood volume was 500 µL from first attempt			4/60 (6,7%)	-	
Number and percentage of cases unsuccessful attempts at blood sampling (two punctuations needed)			1/60 (1,7%)	-	

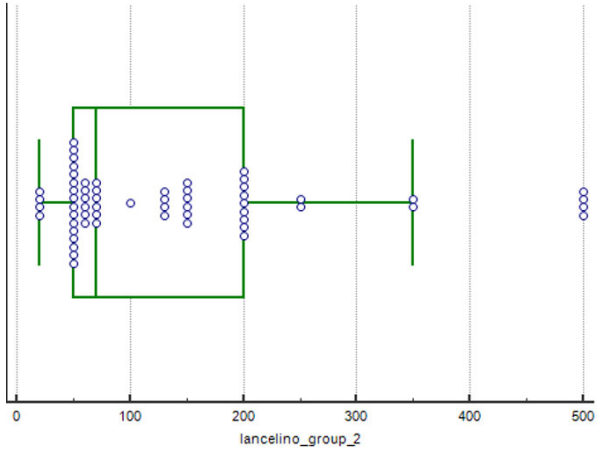

Figure 6. Volume distribution (µL) of capillary blood in **Group 2** after MiniCollect® **Lancelino** Safety Lancets, Item 450522 (21G, penetration depth 1.8mm, blue) were used.

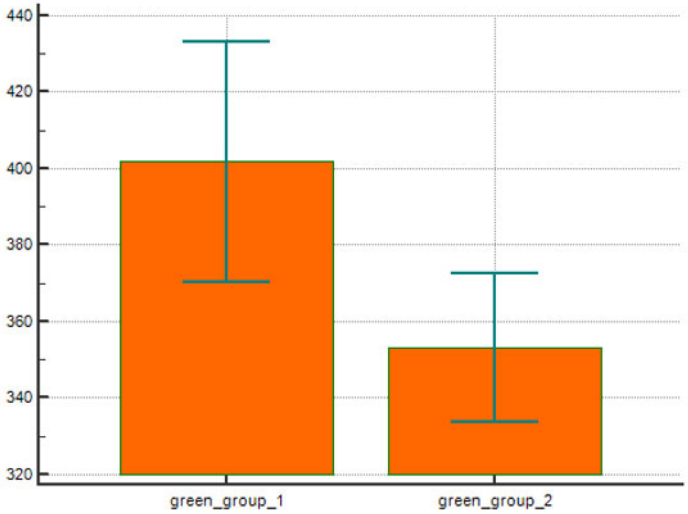

Figure 7. Difference in blood volume using MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm and blade width 1.5 mm, **green**) in two groups (**Group 1 and Group 2**) of participants (**statistically significant difference**).

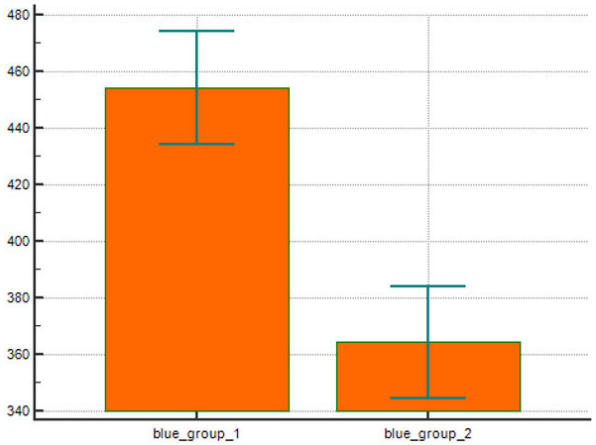

Figure 8. Difference in blood volume obtained using the MiniCollect® automated safety lancets, Item 450429 (penetration depth 2 mm and blade width 1.5 mm, **blue**) in two groups of participants (**Group 1 and Group 2**) of participants (**statistically significant difference**).

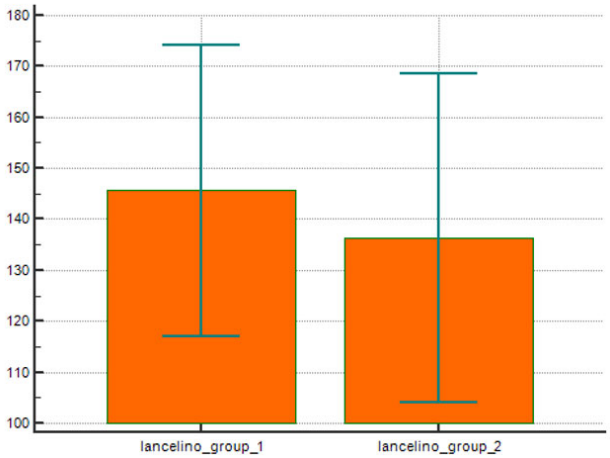

Figure 9: Difference in blood volume obtained using MiniCollect® **Lancelino** automated contact-activated safety lancets number 450522 (21G, penetration depth 1.8 mm, blue) in two groups of participants (**Group 1 and Group 2**) of participants (**no statistically significant difference**).

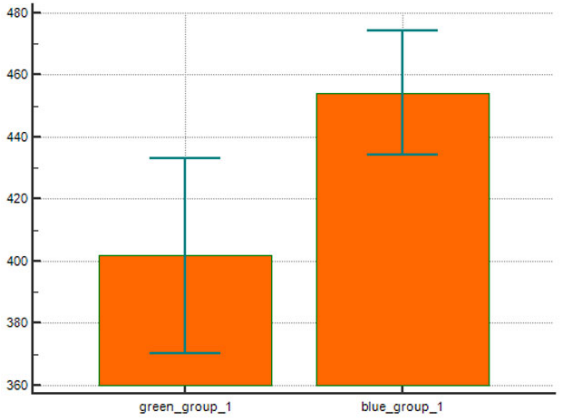

Figure 10 Comparison of blood volume sampled by MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, **blue**) in adults (**Group 1**) (**statistically significant difference**).

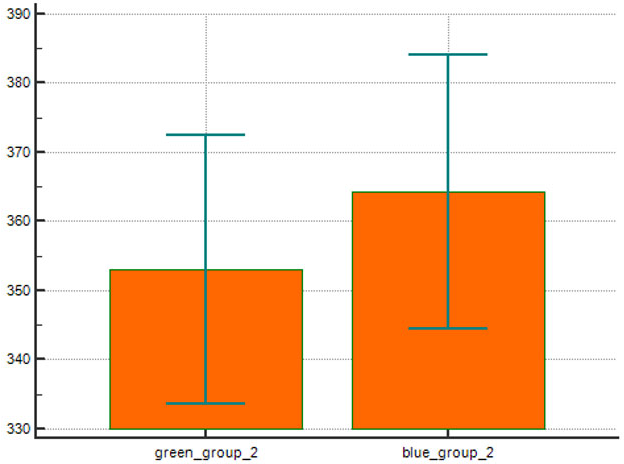

Figure 11 Comparison of blood volume sampled by MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, **blue**) in children (**Group 2**) (**no statistically significant difference**).

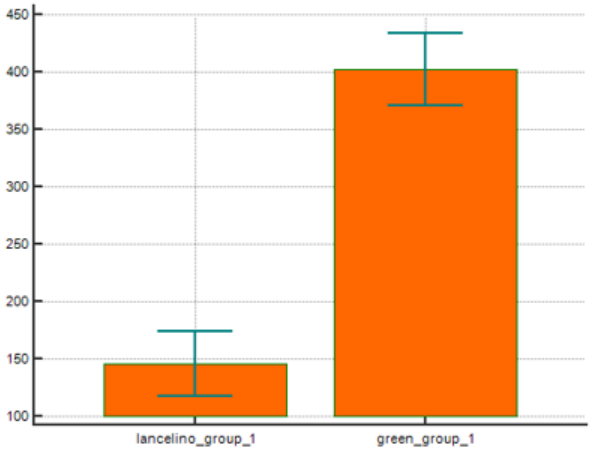

Figure 12 Comparison of blood volume sampled by MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) and MiniCollect® **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in adult population (**Group 1**) (**statistically significant difference**).

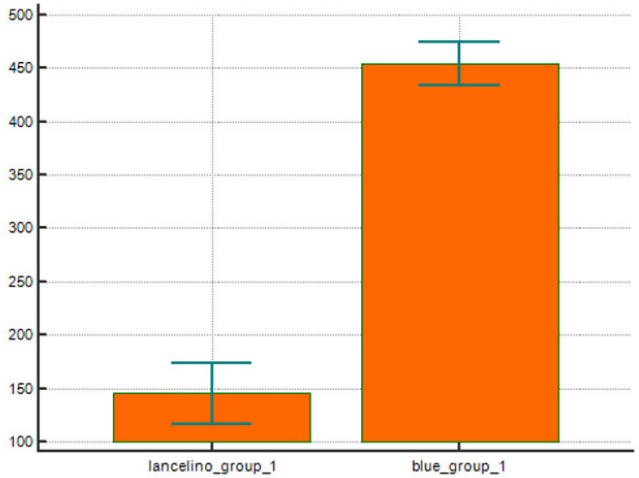

Figure 13 Comparison of blood volume sampled by MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, 1.5 mm blade width, **blue**) and MiniCollect® **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in adult population **(Group 1)** (**statistically significant difference**).

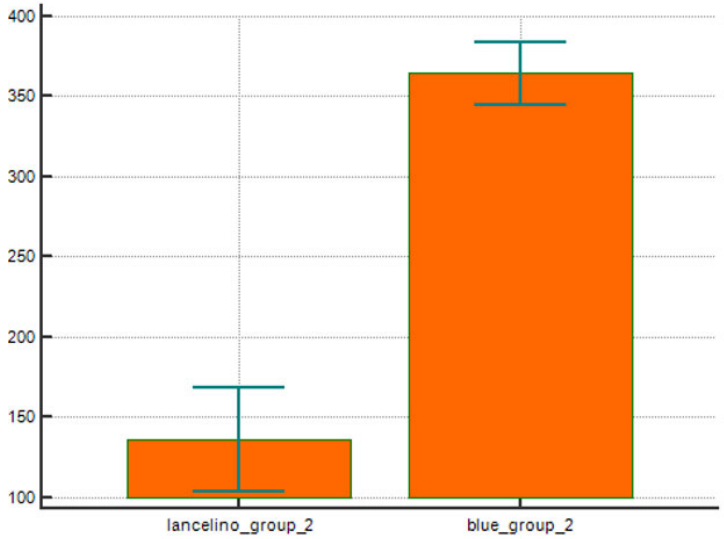

Figure 14 Comparison of blood volume sampled by MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) and MiniCollect® **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in children's population (**Group 2**) (**statistically significant difference**).

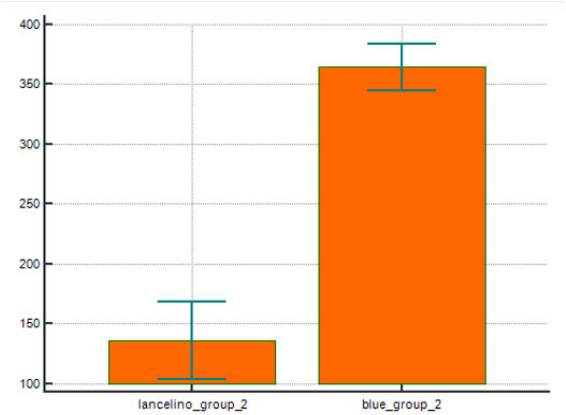

Figure 15 Comparison of blood volume sampled by MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm**, blue**) and MiniCollect® **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) in children's population (**Group 2)** (**statistically significant difference**)**.**

ASSESSMENT OF PAIN DEGREE IN BOTH INVESTIGATION GROUPS

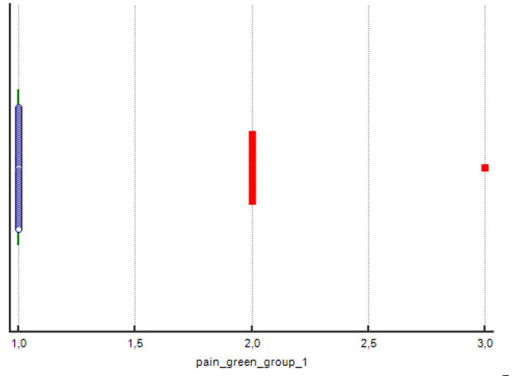

Figure 16 Assessment of pain degree in adult population **(Group 1)** after MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) were used (**level 1: painless / can be ignored**).

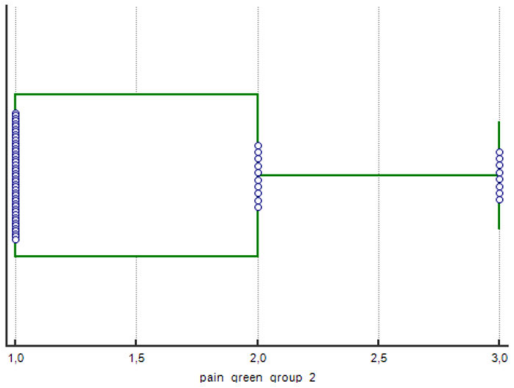

Figure 17 Assessment of pain degree in children's population (**Group 2**) after MiniCollect® automated safety lancets Item 450428 (penetration depth 2 mm, blade width 1.5 mm, blue) were used (**level 1: painless / can be ignored**).

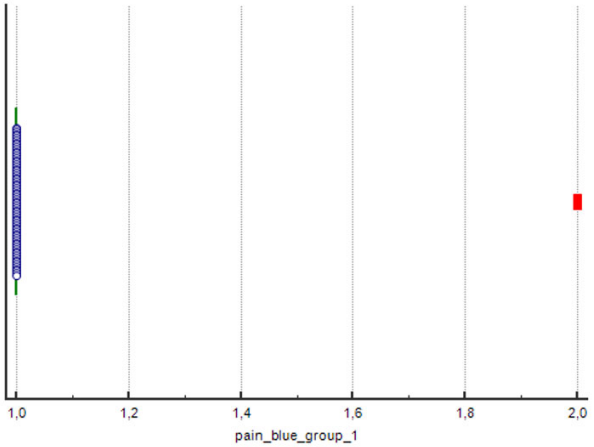

Figure 18 Assessment of pain degree in adult population **(Group 1)** after MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) were used (**level 1: painless / can be ignored**).

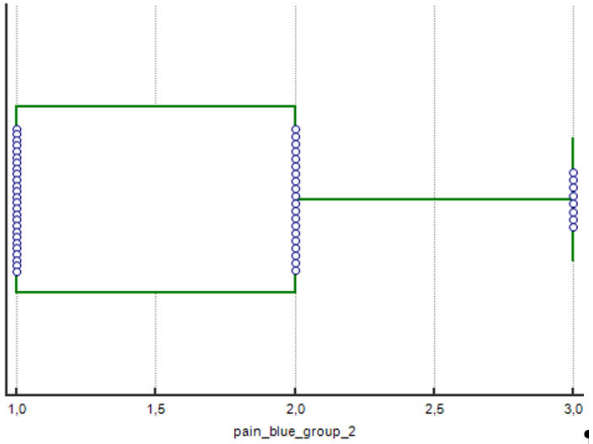

Figure 19 Assessment of pain degree in children's population (**Group 2**) after MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) were used (**level 2: moderate pain / acceptability**).

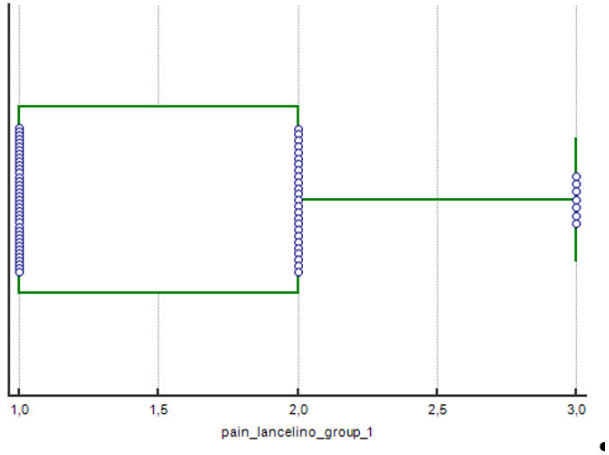

Figure 20 Assessment of pain degree in adult population **(Group 1)** after MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depths 1.8 mm, blue) were used (**level 1: painless / can be ignored by median and level 2: moderate pain / acceptable by mean value**)

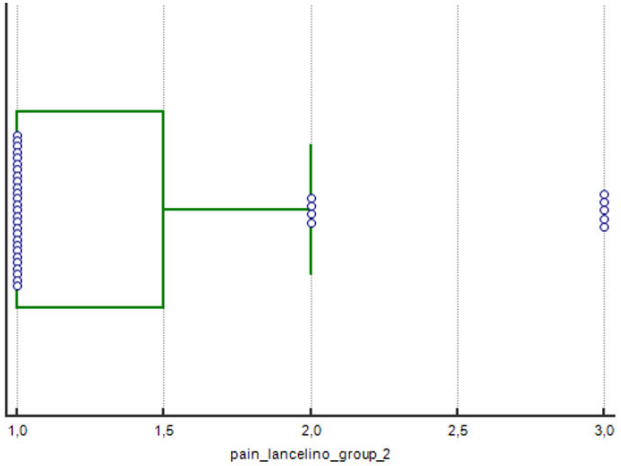

Figure 21 Assessment of pain degree in children's population (**Group 2**) after MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) were used (**level 1: painless / can be ignored**).

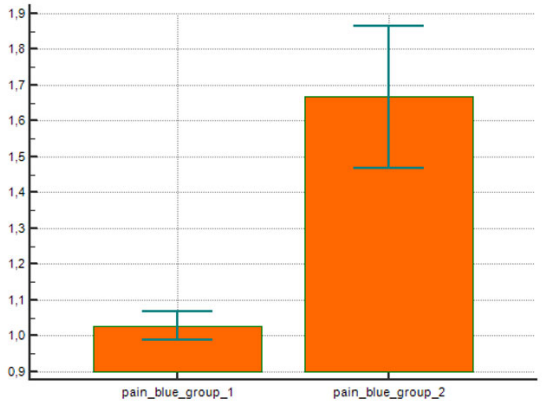

Figure 22 Comparison of estimated pain degree in adult (**Group 1**) and in children's (**Group 2**) population after MiniCollect® automated safety lancets Item 450429 (penetration depth 2 mm, blade width 1.5 mm, blue) were used (**statistically significant difference**).

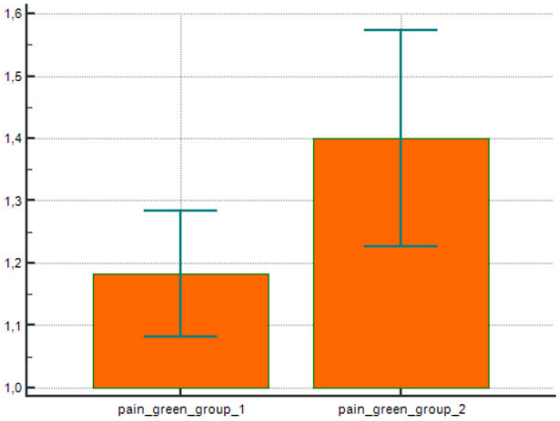

Figure 23 Comparison of estimated pain degree in adult (**Group 1**) and in children's (**Group 2**) population after MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, green) were used (**statistically significant difference**).

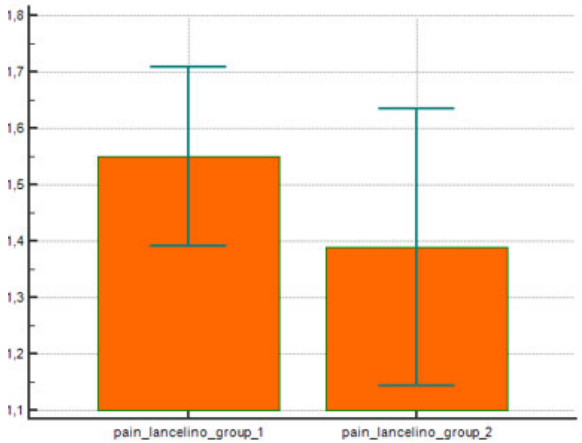

Figure 24. Comparison of estimated pain degree in adult (**Group 1**) and in children's (**Group 2**) population after MiniCollect® Lancelino automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) were used (**no statistically significant difference**).

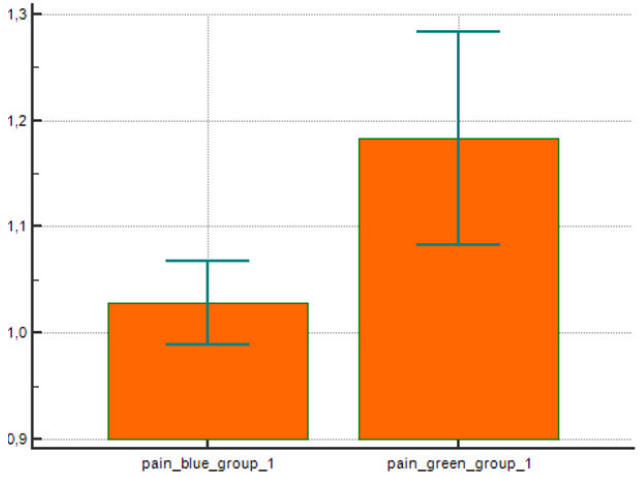

Figure 25. Comparison of estimated pain degree in adult (**Group 1**) after MiniCollect® automated safety lancets Item 450428 (1.5 mm penetration depth, 1.5 mm blade width, **green**) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm**, blue**) were used (**statistically significant difference**).

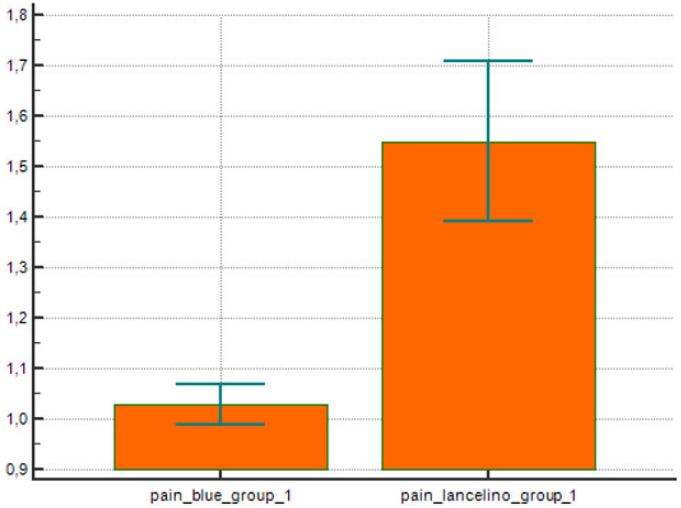

Figure 26 Comparison of estimated pain degree in adult (**Group 1**) after MiniCollect® automated safety lancets Item 450429 (2 mm penetration depth, 1.5 mm blade width, **blue**) and **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) were used (**statistically significant difference**).

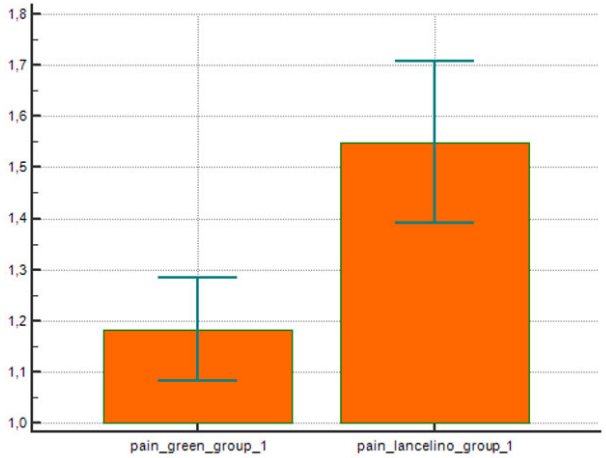

Figure 27 Comparison of estimated pain degree in adult (**Group 1**) after MiniCollect® automated safety lancets Item 450428 (1.5 mm penetration depth, 1.5 mm blade width, **green**) and **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) were used (**statistically significant difference**).

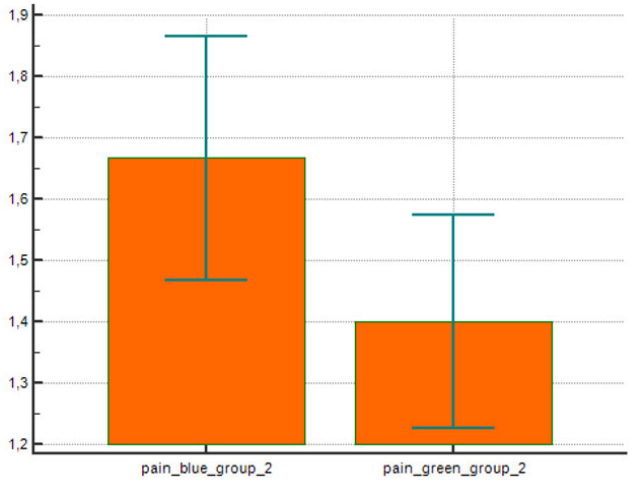

Figure 28 Comparison of estimated pain degree in children's population (**Group 2**) after MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) and Item 450429 (penetration depth 2 mm, blade width 1.5 mm, **blue**) were used (**statistically significant difference**).

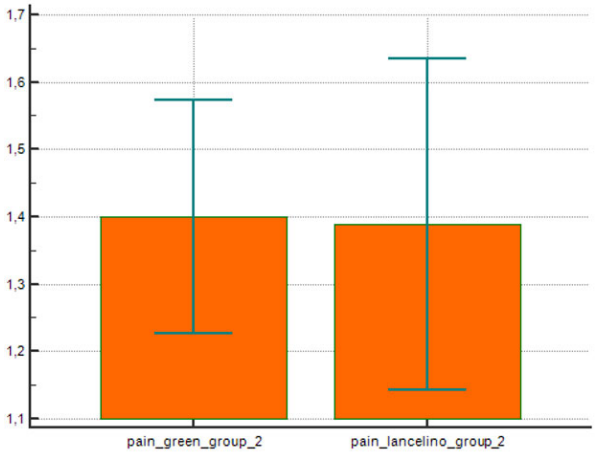

Figure 29 Comparison of estimated pain degree in children's population (**Group 2**) after MiniCollect® automated safety lancets Item 450428 (penetration depth 1.5 mm, blade width 1.5 mm, **green**) and **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) were used (**no statistically significant difference**).

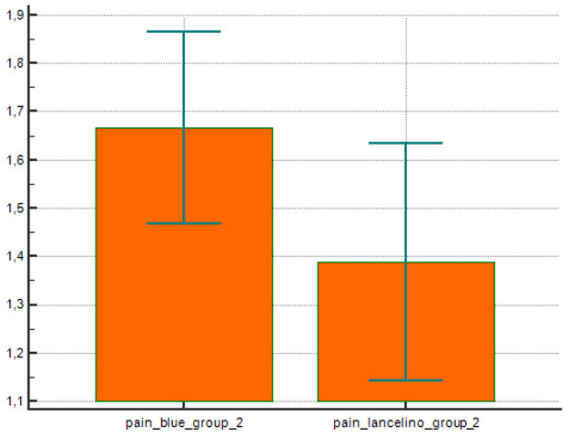

Figure 30 Comparison of estimated pain degree in children's population (**Group 2**) after MiniCollect® automated safety lancets Item 450429 (blade depth 2 mm, blade width 1.5 mm, **blue**) and **Lancelino** automated contact-activated safety lancets Item 450522 (21G, penetration depth 1.8 mm, blue) were used (**no statistically significant difference**).

Evaluation of the pain assessment according to age and lancet types:

	450428-green			450429 - blue			450522 - Lancelino - blue		
	Arithmetic mean	Median	Range	Arithmetic mean	Median	Range	Arithmetic mean	Median	Range
Adult (> 18 years) (Group 1)	1,18 (95% CI: 1,1 - 1,3)	1 (95% CI: 1,0 - 1,0)	1-3	1,02 (95 % CI: 0,98 -1,07)	1 (95% CI: 1,0 - 1,0	1-3	1,55 (95% CI: 1,4 to 1,7)	1 (95% CI: 1,0 to 2,0)	1-3
	1- painless / can be ignored	1- painless / can be ignored		1- painless / can be ignored	1- painless / can be ignored		2- moderate pain / acceptable	1- painless / can be ignored	
Children (< 18 years) (Group 2)	1,4 (95% CI: 1,2 - 1,6)	1,0 (95% CI: 1,0 -1,0)	1-3	1,7 (95% CI: 1,5 -1,9)	2 (95% CI: 1,0 - 2,0)	1-3	1,39 (95% CI: 1,1 -1,6)	1 (95% CI: 1,0-1,0)	1-3
	1- painless / can be ignored	1- painless / can be ignored		2- moderate pain / acceptable	2- moderate pain / acceptable		1- painless / can be ignored	1- painless / can be ignored	

Lancets rating by medical lab staff:

Bachelors of laboratory diagnostics (N=4)	1 - excellent	1 - excellent	2 – very good
Laboratory technicians - trainees (N=2)	1 - excellent	1 - excellent	2 – very good
Bachelors of laboratory diagnostics - trainees (N=3)	1 - excellent	1 - excellent	2 – very good
Master of Medical Biochemistry and Laboratory Medicine - trainees (N=1)	1 - excellent	1 - excellent	2 – very good
Specialist of Medical Biochemistry and Laboratory Medicine - trainees (N=1)	1 - excellent	1 - excellent	2 – very good