

«УТВЕРЖДАЮ»

Генеральный директор
ООО «Медтроник»



Плясунова Е. В.

25 «февраля» 2020 г.

Фотографические изображения

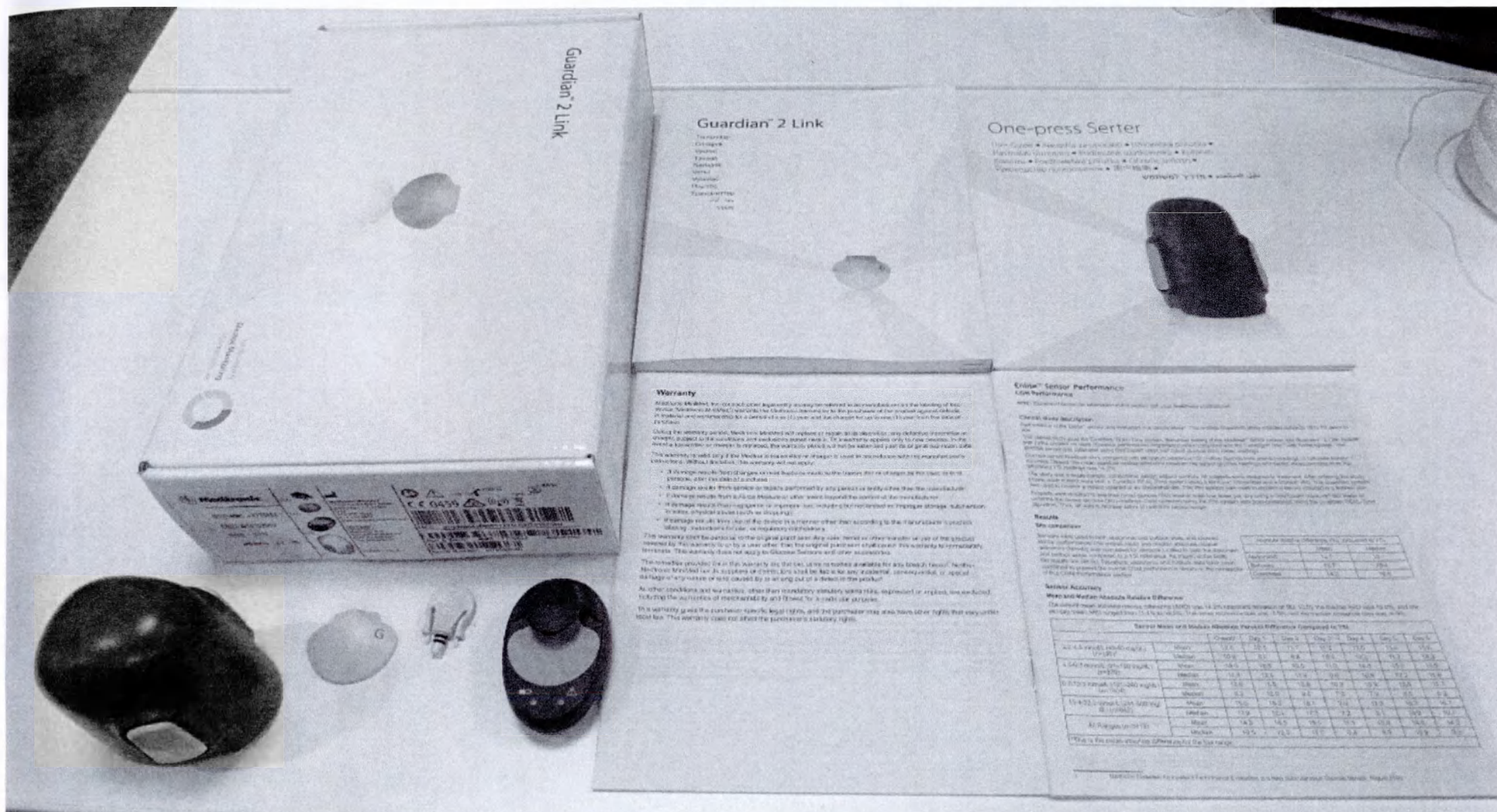
«Трансмиттер Guardian 2 Link в вариантах исполнения»

Производства:

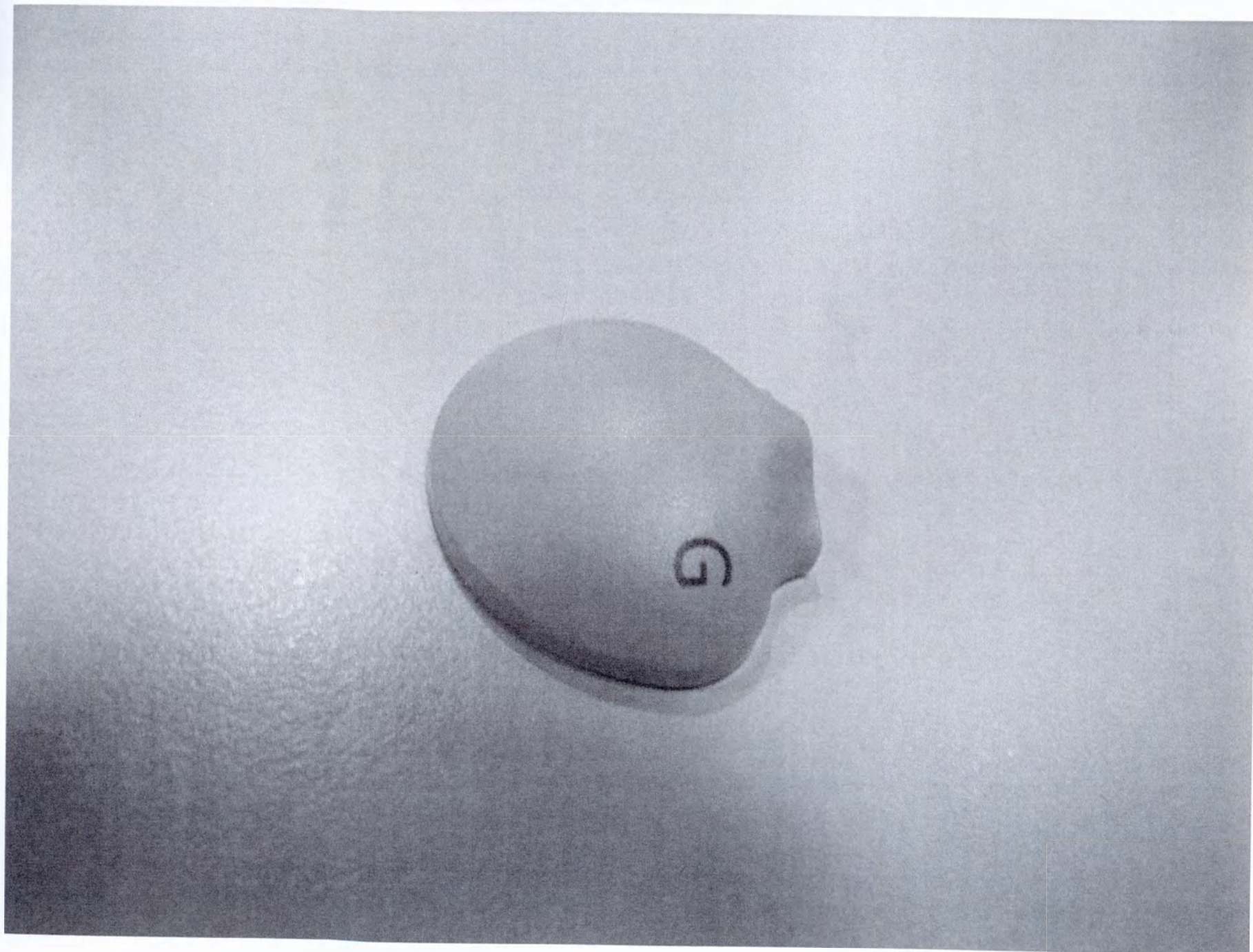
«Медтроник МиниМед», США

Medtronic MiniMed, 18000 Devonshire Street, Northridge, CA 91325, USA

Набор транзмиттера Guardian 2 Link (MMT-7775), в составе:



Трансмиттер Guardian 2 Link (ММТ-7731), верхняя часть корпуса:



Трансмиттер Guardian 2 Link (MMT-7731), нижняя часть корпуса:



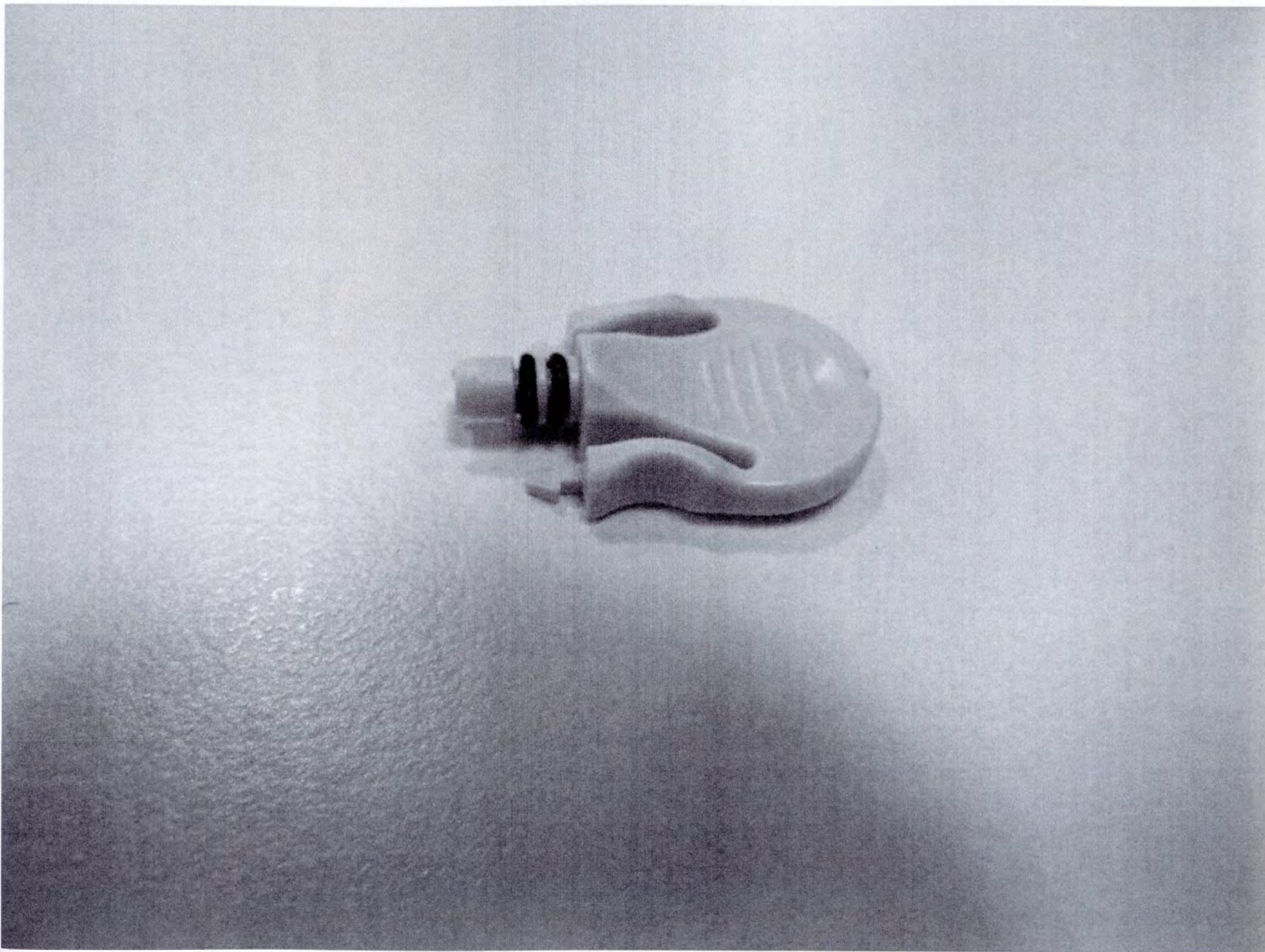
Зарядное устройство (ММТ-7715), верхняя часть корпуса:



Зарядное устройство (ММТ-7715), нижняя часть корпуса:



Водонепроницаемый тестер (ММТ-7726):

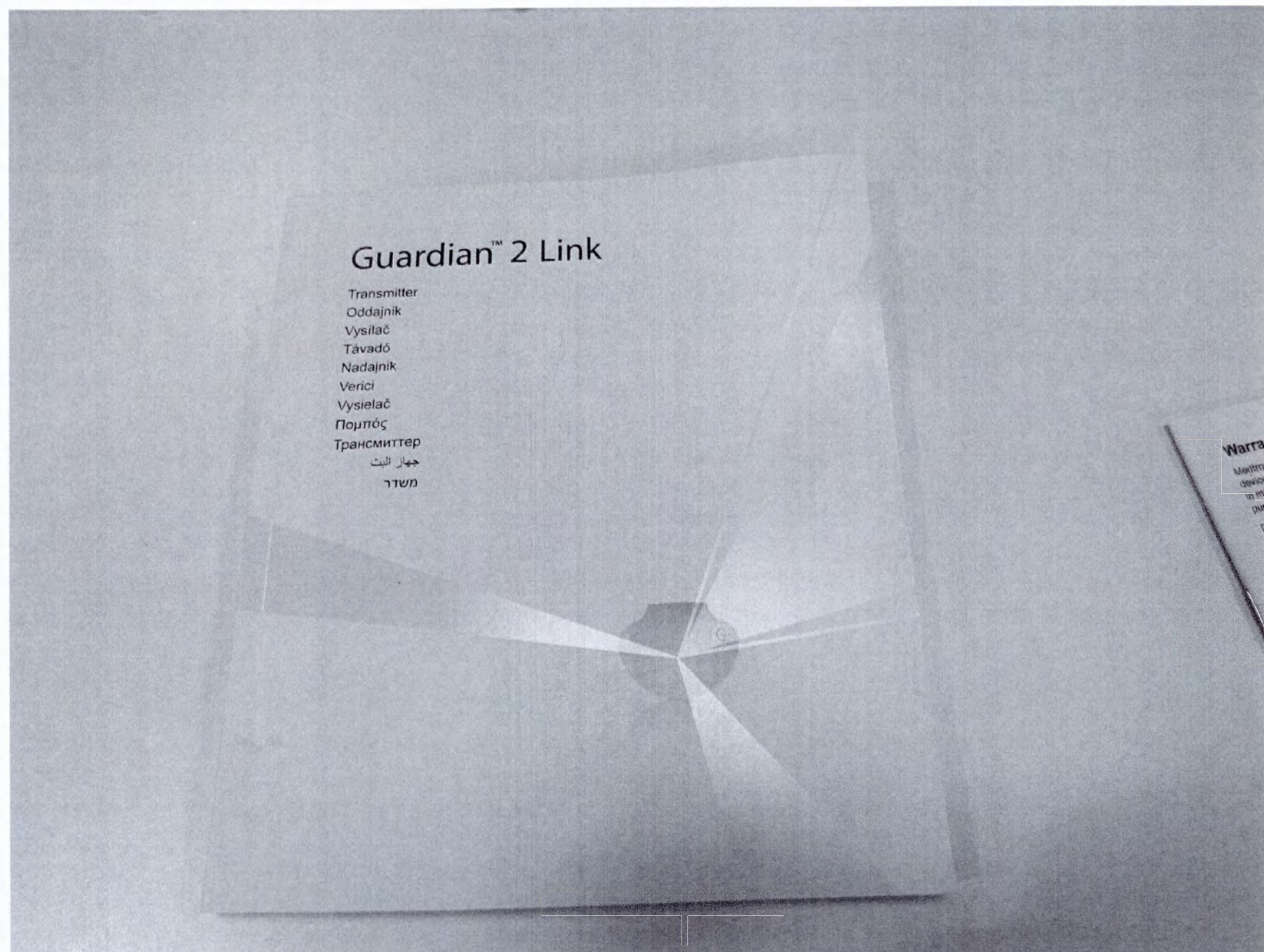


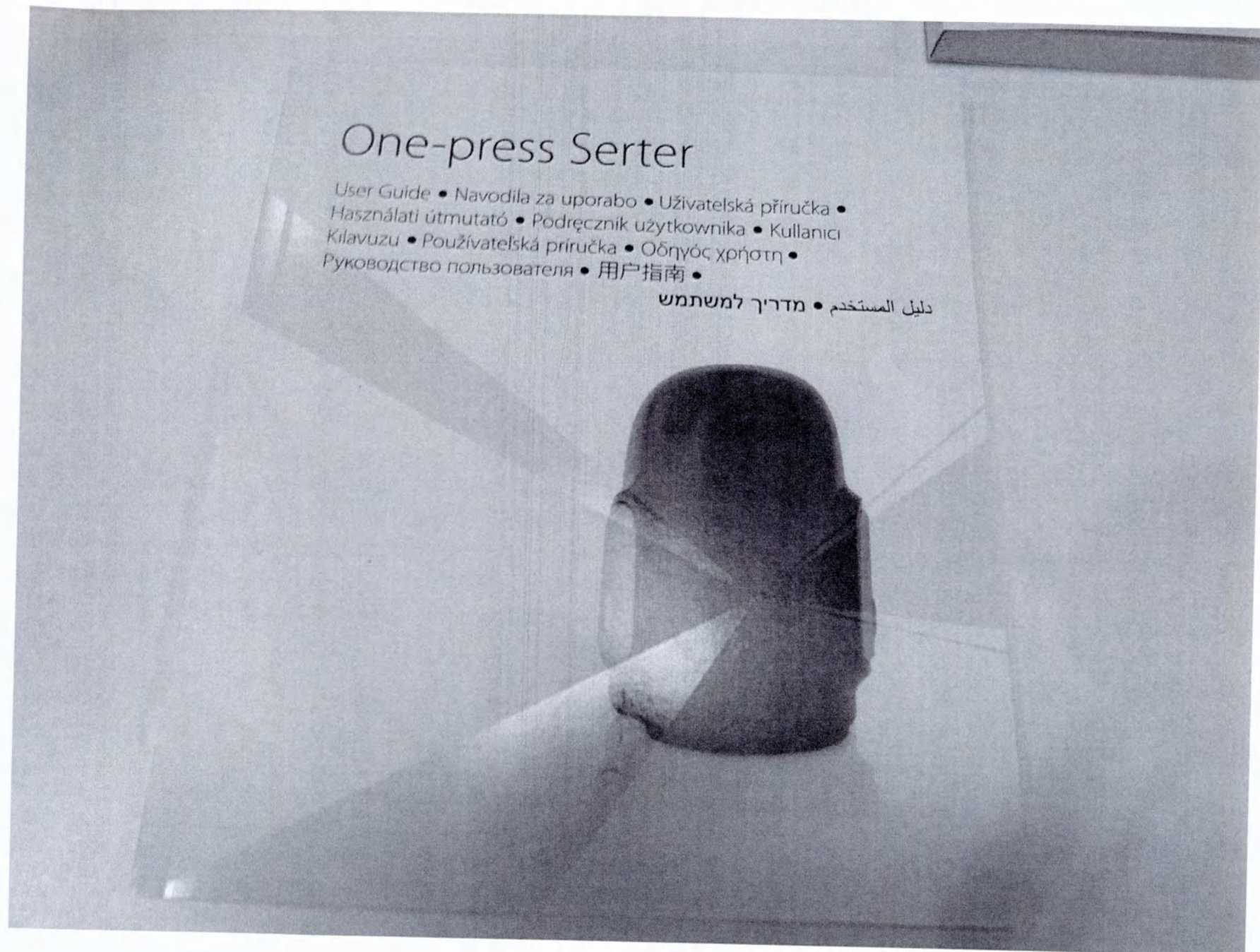
Устройство для установки сенсора One-press Sertter (MMT-7512), передняя сторона:



Устройство для установки сенсора One-press Sertex (MMT-7512), боковая сторона:







Enlite™ Sensor Performance

CGM Performance

NOTE: You should review the information in this section with your healthcare professional.

Clinical study description

Performance of the Enlite™ sensor was evaluated in a clinical study*. This in-clinic (inpatient) study included subjects 18 to 75 years in age.

This clinical study used the Guardian REAL-Time system. Benchtop testing of the MiniMed™ 640G system and Guardian™ 2 Link system with Enlite showed no signs of sensor performance degradation when compared with the Paradigm® Veo™ with Enlite system. The glucose sensor was calibrated using OneTouch® UltraLink® blood glucose (BG) meter readings.

Glucose sensor readings were compared with laboratory reference YSI (Yellow Springs Instruments) readings to calculate sensor accuracy. Overall, the mean absolute relative difference between the sensor glucose readings and paired measurements from the laboratory YSI readings was 14.2%.

The study was a single-sample correlational design without controls. All subjects were assigned to treatment. After entering the study phase, each subject wore both a Guardian REAL-Time system using a MiniLink™ transmitter and a CGMS® iPro. The Guardian system was used to monitor a sensor inserted in an abdominal site. The iPro system was used to monitor a sensor inserted in a buttock site.

Subjects were required to test their blood glucose (BG) level at least four times per day using a OneTouch® UltraLink® BG Meter to calibrate the sensor glucose (SG) readings. Data collected using the iPro system was post-processed using the Guardian REAL-Time algorithm. Thus, all data is representative of real-time sensor usage.

Results

Site comparison

Sensors were used in both abdominal and buttock sites, and showed similar performance. The overall mean and median absolute relative difference (MARD) was calculated for sensors located in both the abdomen and buttock areas compared to a YSI reference. As shown in the table, the results are similar. Therefore, abdominal and buttock data have been combined to present the overall CGM performance results in the remainder of this CGM Performance section.

Absolute relative difference (%) compared to YSI		
	Mean	Median
Abdominal	14.7	10.7
Buttocks	13.7	10.4
Combined	14.2	10.5

Sensor Accuracy

Mean and Median Absolute Relative Difference

The overall mean absolute relative difference (ARD) was 14.2% (standard deviation or SD, 13.0), the median ARD was 10.5%, and the per-day mean ARD ranged from 11.1% to 16.5%. The mean numerical bias was -7.5% and the median numerical bias was -4.9%.

Sensor Mean and Median Absolute Percent Difference Compared to YSI								
		Overall	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
2.2-4.4 mmol/L (40-80 mg/dL) (n=396)*	Mean	12.6	12.3	11.7	11.2	13.6	13.4	15.0
	Median	10.9	8.7	8.8	10.4	12.2	11.7	14.3
4.5-6.7 mmol/L (81-120 mg/dL) (n=876)	Mean	15.0	18.5	16.6	11.0	14.5	15.0	14.9
	Median	11.3	12.4	11.9	9.6	10.5	12.2	11.6
6.7-13.3 mmol/L (121-240 mg/dL) (n=1904)	Mean	12.6	15.5	12.9	10.3	10.9	12.6	11.7
	Median	9.2	12.0	9.6	7.2	7.9	9.5	6.9
13.4-22.2 mmol/L (241-400 mg/dL) (n=642)	Mean	15.0	15.2	18.7	9.9	11.5	15.3	18.1
	Median	11.9	12.1	17.3	7.2	9.1	10.9	10.1
All Ranges (n=3818)	Mean	14.2	16.5	15.1	11.1	13.0	14.4	14.2
	Median	10.5	12.3	11.7	8.4	9.9	10.9	9.3

*This is the mean absolute difference for the low range.

Warranty

Medtronic MiniMed, Inc. (or such other legal entity as may be referred to as manufacturer on the labeling of this device "Medtronic MiniMed") warrants the Medtronic transmitter to the purchaser of the product against defects in material and workmanship for a period of one (1) year and the charger for up to one (1) year from the date of purchase.

During the warranty period, Medtronic MiniMed will replace or repair, at its discretion, any defective transmitter or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a transmitter or charger is replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic transmitter or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the transmitter or charger by the user, or third persons, after the date of purchase;
- If damage results from service or repairs performed by any person or entity other than the manufacturer;
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer;
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water, physical abuse (such as dropping);
- If damage results from use of the device in a manner other than according to the manufacturer's product labeling, instructions for use, or regulatory notifications.

This warranty shall be personal to the original purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original purchaser shall cause this warranty to immediately terminate. This warranty does not apply to Glucose Sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other conditions and warranties, other than mandatory statutory warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

This warranty gives the purchaser specific legal rights, and the purchaser may also have other rights that vary under local law. This warranty does not affect the purchaser's statutory rights.

Трансмиттер Guardian 2 Link (ММТ-7738), в составе:



Макет маркировки медицинского изделия:

	Трансмиссер Guardian 2 Link в вариантах исполнения	
	Производитель:	Код UPN
	Страна происхождения:	Код CFN
	Представитель производителя в РФ:	
	Регистрационное Удостоверение №___ от___	
	Дата изгот./Серия/Годен до: см. упаковку	См. Инструкцию С. символы на упаковке

Всего прошнуровано,
пронумеровано и скреплено
печатью ООО "Медтроник"
15 листа(ов)

