- 1 Original Article
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4 Reliability of a smartphone electrocardiogram device in dogs: comparison with standard
 5 6-lead electrocardiography

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 7 T. Vezzosi ^{a,*}, C. Buralli ^a, F. Marchesotti ^b, F. Porporato ^b, R. Tognetti ^a, E. Zini ^{b, c, d}, O.
 8 Domenech ^b
- 9
- ¹⁰ ^a Department of Veterinary Science, University of Pisa, via Livornese lato monte, 56122 San
- 11 Piero a Grado, Pisa, Italy
- ^b Istituto Veterinario di Novara, Strada Provinciale 9, 28060 Granozzo con Monticello,
 Novara, Italy
- ^c Clinic for Small Animal Internal Medicine, Vetsuisse Faculty, University of Zurich,
- 15 Winterthurerstrasse 260, CH-8057, Zurich, Switzerland
- ¹⁶ ^d Department of Animal Medicine, Production and Health, University of Padova, Viale
- 17 dell'Universita' 16, 35020 Legnaro, Padova, Italy
- 18
 19 * Corresponding author. Tel.: +39 0502210158.
- 20 *E-mail address:* tommaso.vezzosi@vet.unipi.it (T. Vezzosi).

22 Abstract

23 A prospective, multicenter, single-blind study was conducted in 166 dogs to assess the 24 reliability of a smartphone electrocardiogram (ECG) device in evaluating heart rhythm and 25 ECG measurements. A standard 6-lead ECG was acquired for 1 min in each dog. A 26 smartphone ECG tracing was simultaneously recorded using a single-lead bipolar ECG 27 recorder. All ECGs were reviewed by one blinded operator, who judged if tracings were 28 acceptable for interpretation and assigned an electrocardiographic diagnosis. Agreement 29 between smartphone and standard ECG in the interpretation of tracings was evaluated. 30 Sensitivity and specificity for the detection of arrhythmia were calculated with the 31 smartphone ECG. 32 Smartphone ECG tracings were interpretable in 162/166 (97.6%) tracings. A perfect 33 agreement between the smartphone and standard ECG was found in detecting bradycardia, 34 tachycardia, ectopic beats and atrioventricular blocks. A very good agreement was found in 35 detecting sinus rhythm versus non sinus rhythm, with a 100% sensitivity and 97.9% 36 specificity. The smartphone ECG provides tracings that are adequate for analysis in most dogs 37 with a reliable assessment of heart rate, heart rhythm, atrioventricular blocks or ectopic beats. 38 The smartphone device represents an additional tool in the management of dogs with 39 arrhythmias, but does not substitute a 6-lead ECG. Arrhythmias identified by the smartphone 40 device should be followed up with a standard ECG before taking clinical decisions. 41

42

43 Keywords: Alivecor; Canine; Electrocardiography; iPhone; Mobile

44 Introduction

Many arrhythmias have paroxysmal presentation, while others require frequent
monitoring due to the risk of progression. In these settings, serial electrocardiograms (ECG)
are crucial for correct diagnosis and management. Clinical electrocardiography has thus
undergone a continuous technological evolution since its invention by Willem Einthoven in
1903, leading to the development of Holter monitoring, telemetry systems and loop recorders
(Kennedy, 2013).

51

52 One of the latest innovations is the 1-lead ECG recorded by smartphone devices using 53 specific applications (Bruining et al., 2014; Walsh et al., 2014; Baguero et al., 2015). In 54 human medicine there are many studies highlighting the accuracy of smartphone ECG 55 tracings to measure the heart rate (HR) and evaluate heart rhythm (Lau et al., 2013; Ho et al., 56 2014; Haberman et al., 2015). Other studies have shown the good performances of 57 smartphone ECG devices for diagnosing supraventricular tachycardia in pediatrics (Wackel et 58 al., 2014; Ferdman et al., 2015; Nguyen et al., 2015), for detecting atrial fibrillation (Lau et 59 al., 2013; Lee et al., 2013; McManus et al., 2013; Saxon, 2013; Orchard et al., 2014; Lowres 60 et al., 2015a) and for identifying signs associated with myocardial ischemia (Wong, 2013). To 61 the best of our knowledge only one preliminary study has been performed comparing a 62 smartphone ECG device to standardized ECG tracings in dogs (Kraus et al., 2013). The aim 63 of the present study was therefore to assess the use and reliability of a smartphone ECG to 64 evaluate heart rhythm and ECG measurements in dogs.

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66 Materials and methods

67 Animals

68 The study group included client-owned dogs that were referred to the Department of 69 Veterinary Science of the University of Pisa or the Department of Cardiology of the Istituto 70 Veterinario di Novara for a cardiologic consultation or assessment prior to anesthesia. The 71 study was prospective, multicenter and single-blind. Dogs were recruited over a one-year 72 period (December 2014-December 2015). Each case underwent a cardiac evaluation, 73 including physical examination, standard 6-lead ECG and echocardiogram. The study 74 protocol was reviewed and approved by the Institutional Welfare and Ethics Committee of the 75 University of Pisa (permission number 39/2015).

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77 ECG acquisition and analysis

A standard 6-lead ECG (Elan 1100 ECG system, Cardioline; MAC 800 ECG system, 78 79 GE Healthcare) was acquired for 1 min in conscious, unsedated dogs positioned in right 80 lateral recumbency. Surface electrodes made of flattened alligator clips were attached to the 81 skin at the level of the olecranon on the caudal aspect of the forelimb, and over the patellar 82 ligaments on the cranial aspect of the hindlimbs, as previously described (Tilley, 1992). 83 Rubbing alcohol was applied to maintain electrical contact with the skin. A sampling 84 frequency of 1000Hz for standard ECG acquisition was used, with a 100 Hz low-pass filter 85 and a 0.5 Hz high-pass filter to decrease respiratory artifact, as previously published 86 (Hinchcliff, et al. 1997).

A smartphone ECG tracing was simultaneously recorded, starting and ending at the same time of the 6-lead ECG, using a single-lead bipolar ECG recorder (AliveCor Veterinary Heart Monitor, AliveCor, Inc.) and its application (AliveECG Vet, AliveCor, Inc.). Three operators (TV, CB, FM) recorded the smartphone ECGs with an iPhone 4S (Apple Inc.). The smartphone ECG was recorded placing it on the left precordial area of all the dogs. A craniocaudal orientation of the smartphone case was used in each dog, with the camera side of the

93 smartphone located caudally (Fig. 1). In the short-haired dogs, a small amount of alcohol was 94 placed on the left precordial area in order to obtain a good quality smartphone ECG signal. In 95 the long-haired dogs, a small amount of alcohol was placed after shaving the left precordial 96 area in order to acquire the same high-quality signal. Smartphone ECG recordings were 97 automatically digitized by the device, sent via email and stored as a PDF file. For each dog, 98 ECG tracings obtained with the two methods were printed at a paper speed of 50 mm/s with a 99 gain of 10 mm/mV. The last 30 s of each ECG tracing were analyzed. Dogs with a 100 smartphone ECG trace lasting < 30 s were excluded from the study.

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All ECG tracings were reviewed by a board-certified veterinary cardiologist (OD), in a
blinded fashion, who judged whether the tracings were acceptable for interpretation. For all
ECG tracings, the same operator evaluated the rhythm and performed ECG measurements.
Measurements were achieved using the lead II of the standard ECG and using the only
available lead of the smartphone ECG.

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108 In each case, the following measurements were performed: mean HR (beats per min, 109 bpm); P wave amplitude (mV) and duration (ms); PQ interval duration (ms); R wave 110 amplitude (mV); QRS complex duration (ms) and QRS polarity. The mean HR was calculated 111 as the number of QRS complexes recorded in the 1 min ECG tracings (bpm). Other 112 measurements were achieved as previously described (Kittleson and Kienle, 1998). The QRS 113 polarity of the smartphone ECG traces was compared with lead II of the standard ECG. 114 Finally, the mean HR calculated automatically by the smartphone application (App HR) was 115 noted. Heart rate was classified as normal if between 70 and 160 bpm, bradycardia if < 70116 bpm and tachycardia if > 160 bpm, as previously described (Kittleson and Kienle, 1998). 117

119 The analysis was performed only with paired ECG tracings that were considered 120 acceptable for interpretation, as defined by the operator, and the standard ECG was set as the 121 reference method. Cohen's kappa (κ) test was used to calculate the agreement between the 122 smartphone ECG and standard ECG for HR classification (normal, bradycardia or 123 tachycardia), heart rhythm (sinus rhythm, atrial fibrillation, ventricular rhythm, 124 supraventricular rhythm), atrioventricular blocks (AVB) (absent, first-degree AVB, second-125 degree AVB, third-degree AVB), premature complexes (absent, ventricular, supraventricular), 126 polarity of QRS complex (positive, negative). The kappa coefficient was interpreted as 127 follows: values ≤ 0.20 as no agreement, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 128 as good, 0.81–0.99 as very good, and 1 as perfect agreement. The sensitivity, specificity, 129 positive and negative predictive values of the smartphone ECG to detect arrhythmia were 130 calculated. In addition, the median and range of differences between the standard ECG and 131 smartphone ECG were calculated for HR, amplitude of the P and R waves, for the duration of 132 the P wave, PQ interval, QRS complex. Bland-Altman plots were used to show the 133 differences between smartphone and standard ECG for numerical data. The Pearson or 134 Spearman correlation coefficients were used to study correlations between HRs measured 135 with the standard ECG and the smartphone ECG using values calculated either by the 136 operator or automatically. The Shapiro-Wilk test was used to determine the normality of the 137 datasets.. Statistical analysis was performed with a commercial software (GraphPad Prism 5). P

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139 < 0.05 was considered as significant.

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141 Results

142 Animals and feasibility A total of 166 dogs were enrolled in the study, of which 84 were males and 82 were females. The median age was nine years (ranging between 0.3 to 17 years) and median body weight was 25 kg (55.1 lb) with a range of 2.1 to 75 kg (4.6 to 165.3 lb). The majority of dogs (71/166, 43%) had cardiac diseases, both congenital or acquired; 32/166 (19%) dogs had neoplastic diseases, 30/166 (18%) were in the intensive care unit because of renal, respiratory, gastro-intestinal or neurologic diseases, and 33/166 (20%) were healthy dogs evaluated for pre-anesthesia assessment prior to elective surgeries.

The blinded operator judged 162/166 (97.6%) of the smartphone ECG tracings as acceptable for interpretation (Fig. 2, 3 and 4). In 4/166 (2.4%) cases the traces were deemed as non-interpretable; all 4 of the traces deemed uninterpretable were obtained from patients weighing <10kgs.

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155 Heart rate

156 According to the standard 6-lead ECG, 133/162 (82%) dogs had a normal HR, 20/162 157 (12%) had tachycardia, and 9/162 (6%) had bradycardia. A perfect agreement (κ =1) between 158 the smartphone and standard ECG was found in the classification of HR when it was 159 manually measured on digitized tracings (Table 1). A strong positive correlation was found 160 between the HR values manually measured on standard ECGs and smartphone ECG tracings 161 $(r^2 = 0.99; P < 0.0001; Fig. 5)$. Median paired differences between the HR manually measured 162 on standard ECG and smartphone ECG was 0 bpm (-10, +20 bpm; Table 2 and Fig. 6). 163 A strong positive correlation was also found between the App HR values and those manually measured on standard ECG tracings ($r^2 = 0.923$; P < 0.0001; Fig. 7). However, the 164 165 App HR was less accurate than the manually measured HR on digitized standard ECG 166 tracings (κ =0.91). In 103/162 (63.6%) cases, the App HR underestimated the actual HR, with 167 a median difference of -3 bpm; (-31, +20 bpm; Fig. 8). However in only 4/162 (2.5%) cases,

168 was there a misclassification of HR with the smartphone application. According to App HR, 169 two dogs with tachycardia were classified as normal HR, one dog with normal HR was 170 classified as bradycardia, and one dog with bradycardia was classified as normal HR. The 171 greatest disagreement was found in a dog with severe bradycardia (40 bpm) secondary to a 172 third-degree AVB in which the App HR read the P waves as QRS complexes, thus 173 erroneously yielding an HR of 140 bpm. 174 175 Heart rhythm 176 The majority of dogs (141/162, 87%) had sinus rhythm or sinus arrhythmia; 14/162 177 (9%) dogs had supraventricular arrhythmias; 7/162 (4%) dogs had ventricular rhythm or 178 ventricular arrhythmias; 6/162 (4%) dogs had different types of AVBs. 179 Very good agreement (κ =0.94) was found in the evaluation of the heart rhythm. 180 Disagreement was found in only 3/162 (1.9%) cases, in which the sinus rhythm was 181 erroneously classified as atrial rhythm due to the negative polarity of the P waves (one case) 182 or as a slow atrial fibrillation due to non observable P waves (two cases) on the smartphone 183 ECG trace (Table 3). In 128/141 (90.7%) cases of sinus rhythm, the smartphone ECG 184 underestimated the amplitude of the P wave, with a median difference of -0.1 mV (-0.4; +0.1 185 mV). The analysis of the P wave duration showed a median difference between the two 186 methods of 0 ms (-20, +0 ms). 187 Considering all the arrhythmias taken together, the smartphone ECG had 100% 188 sensitivity and 97.9% specificity in differentiating between sinus rhythm versus non sinus 189 rhythm, with a positive predictive value of 87.5%, and a negative predictive value of 100%.

191 *QRS complex analysis*

192 A good agreement (κ =0.65) was found in the polarity of the ORS complexes between 193 the smartphone ECG and lead II of the standard 6-lead ECG (Fig. 2, 3, 4). The same QRS 194 polarity was found in 158/162 (97.5%) cases. In three cases with positive polarity of the QRS 195 complex in lead II, the smartphone tracing showed a negative QRS. In one case with negative 196 polarity of the ORS complex in lead II, the smartphone tracing showed a positive ORS. The 197 evaluation of the QRS duration showed a median difference of 0 ms (-20, +10 ms). Lastly, the 198 smartphone ECG underestimated the amplitude of R wave in 121/162 (74.7%), with a median 199 difference of -0.5 mV (-2.1; +1 mV), compared to the standard ECG.

200

201 Ectopic beats

A perfect agreement (κ =1) between the smartphone ECG and standard ECG was found in the identification and classification of ectopic beats, including 16 cases with ventricular premature complexes, three cases with supraventricular premature complexes and four cases with both supraventricular and ventricular ectopic beats. In addition a perfect agreement was found regarding the polarity of ventricular premature complexes on the smartphone ECG tracings compared with lead II of the standard 6-lead ECG.

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209 Atrioventricular blocks

A perfect agreement (κ =1) between the smartphone ECG and standard ECG was found in the AVB diagnosis, including two cases with first-degree AVB, one with second-degree AVB and three cases with third-degree AVB. The PQ interval analysis using smartphone tracings was reliable in comparison to the standard ECG, with a median difference of 0 ms (range -20, +20 ms).

216 **Discussion**

In our investigation the smartphone ECG was easily performed in all dogs and 96.7% of tracings were deemed as interpretable. These results are in line with findings in human medicine where smartphone ECG tracings were interpretable in 87-99% of patients (Saxon, 2013; Nguyen et al., 2015; Tarakji et al., 2015). The few tracings judged as non-interpretable were all recorded in small breed dogs, where motion artifacts are common, which likely accounted for the fact that the tracings were not readable.

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224 In our study, the smartphone ECG was excellent in the HR evaluation in dogs. This is 225 in accordance with a preliminary study in dogs, where a good agreement was found between 226 smartphone ECG and reference ECG in the evaluation of instantaneous and mean HR (Kraus 227 et al., 2013). In our investigation, the greatest reliability was found when the HR was 228 manually measured on digitized tracings. Conversely the App HR was less reliable, since 229 lower agreement was found between the HR values obtained by the smartphone device and 230 the standard ECG. As the QRS complexes on smartphone ECG tracings had a low amplitude 231 in most dogs, we hypothesize that the App HR may underestimate the HR due to the fact that 232 some QRS complexes are not correctly interpreted by the instrument. In a few dogs, the App 233 HR was totally unreliable. However, in only one case the disagreement was of a real clinical 234 value: in a dog with severe bradycardia secondary to third-degree AVB, the App HR read the 235 P waves as QRS complexes, thus erroneously resulting in a normal HR.

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The smartphone ECG was very reliable in evaluating heart rhythm in dogs, as it showed 100% sensitivity and 97.9% specificity in the detection of arrhythmias. All cases of atrial fibrillation were correctly diagnosed, without false negatives. This result is similar to findings in humans where the sensitivity and specificity of the smartphone ECG in detecting

241 atrial fibrillation were 94-100% and 90-97%, respectively (Lau et al., 2013; Haberman et al., 242 2015; Tarakji et al., 2015). In humans, most false diagnoses of atrial fibrillation are due to 243 small voltage P waves. Our results showed that the smartphone ECG underestimates the 244 amplitude of the P wave. Despite this, the P waves remained clearly visible in the majority of 245 dogs with sinus rhythm. In a few cases, however, the P waves were difficult to recognize and 246 it was hard to determine between a sinus arrhythmia and atrial fibrillation. Consequently, two 247 out of 141 cases of sinus rhythm were incorrectly classified as atrial fibrillation. In a small 248 breed dog, the P waves had negative polarity on the smartphone ECG leading to the incorrect 249 diagnosis of an atrial ectopic rhythm. A preliminary study in cats recommended positioning 250 the smartphone case parallel to the long axis of the heart, with a more base-apex orientation in 251 comparison to our cranio-caudal orientation (Stromberg and Kvart, 2015). It might be that in 252 some small breed dogs, the orientation of the smartphone case should be individually adjusted 253 to correctly visualize the P waves.

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255 Atrial fibrillation is common in dogs with severe cardiac disease and increases the risk 256 of cardiac-related death in those with myxomatous mitral valve degeneration and dilated 257 cardiomyopathy (Calvert et al., 1997; Jung et al., 2016). Likewise, in humans, atrial 258 fibrillation increases the chance of morbidity or mortality, and recent studies have highlighted 259 the utility of the smartphone ECG in screening for this arrhythmia (Lau et al., 2013; Lee et al., 2013; McManus et al., 2013; Saxon, 2013; Orchard et al., 2014; Lowres et al., 2015b 260 261 Haberman et al., 2015; Peritz et al. 2015;). Early diagnosis of atrial fibrillation is difficult in 262 dogs. Our results show that the smartphone ECG may become a promising tool for frequent 263 monitoring of dogs predisposed to atrial fibrillation. It could also be beneficial for dogs with 264 atrial fibrillation that receive drugs to control HR. Holter monitoring is an essential tool for 265 evaluating HR and in treating atrial fibrillation in dogs. However, 24-hour Holter monitoring

is expensive and necessitates the owner's compliance, hence its use may not always be
practical. In the light of its ease and cost effectiveness, the smartphone ECG could represent a
complementary tool for HR evaluation at home in dogs with atrial fibrillation.

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270 The smartphone ECG showed a good reliability in the analysis of the QRS complex, in 271 assessing both duration and polarity. In most dogs, QRS complexes displayed the same 272 polarity on smartphone tracings and lead II of the 6-lead ECG, with a similar polarity in all 273 cases of ventricular ectopic beats. In comparison to the standard ECG however, the 274 smartphone device underestimated the R wave amplitude. In fact, wave amplitudes are 275 extremely dependent on the electrocardiographic derivation method. Further studies are 276 needed to establish reference values of wave amplitudes on smartphone ECG tracings. 277 In our opinion, smartphone tracings should not be used to assess the amplitude of ECG 278 waves as a substitute for standard electrocardiograms and as a diagnostic method in the 279 detection of chamber enlargement. 280 281 The smartphone ECG was highly reliable in the identification of ectopic beats. 282 Ventricular premature complexes, accelerated idioventricular rhythms and ventricular 283 tachycardias were easily identified in all cases with the smartphone ECG. One recent 284 investigation used it as the sole electrocardiographic method in the identification of 285 ventricular premature complexes in the screening of Doberman Pinschers for occult dilated 286 cardiomyopathy (Gordon et al., 2015). It could thus be useful in screening or monitoring dogs 287 with cardiomyopathies associated with ventricular arrhythmias. 288

With regard to the reliability of the smartphone ECG for AVBs, a good agreement with the standard ECG was found both in the evaluation of the PQ interval and in the

identification of the type of block. One study in humans described a higher percentage of false
positives and negatives during the evaluation of AVBs compared to our results (Haberman et
al., 2015). The authors reported motion artifacts (arm movement, muscle tension and tremor)
as the main difficulties in AVB evaluation. None of the smartphone ECG tracings recorded
motion artifacts that led to misdiagnosing AVBs. Thus, the agreement between devices was
perfect, suggesting that the smartphone ECG can be helpful in the interpretation of AVBs in
dogs.

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Our investigation has some limitations. First, the study group was large but the number of dogs with arrhythmias was relatively low. A larger number of rhythm disturbances might have revealed a lower reliability of the smartphone ECG. However, most common types of canine arrhythmias were included in our study and in all these cases the smartphone ECG was consistent in diagnosing the arrhythmia. Second, the smartphone tracings were acquired by three operators but inter-operator variability in the quality of ECG recording was not evaluated.

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307 Conclusion

In conclusion, the smartphone ECG can rapidly and simply record a single-lead ECG
of good diagnostic quality in dogs. Tracing analysis performed by cardiologists reliably
evaluated HR, heart rhythm, AVBs and ectopic beats.

The smartphone device does not substitute the 6-lead ECG or Holter monitoring but does represent an additional tool in the management of dogs with arrhythmias or in monitoring dogs at risk for heart rhythm disturbances. Therefore, any arrhythmia identified by the smartphone device should be followed by a standard 6-lead ECG and treatment decisions based upon smartphone ECG only are not recommended.

316	Further studies are needed to assess the diagnostic value of the smartphone ECG
317	recorded by owners in a home setting.
318	
319	Conflict of interest statement
320	None of the authors has any financial or personal relationships that could
321	inappropriately influence or bias the content of the paper.
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441 **Table 1**

442 Agreement (κ) between smartphone ECG and standard 6-lead ECG.

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Type of analysis	к (95% CI)		Agreement	
Manual HR	1		Perfect	
App HR	0.91	(0.81-0.99)	Very good	
Heart rhythm	0.94	(0.86-1)	Very good	
AVBs	1		Perfect	
Ectopic beats	1		Perfect	
QRS polarity	0.65	(0.34 to 0.97)	Good	

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445 App HR, heart rate automatically measured by smartphone application; AVBs,

446 atrioventricular blocks; CI, confidence interval; Manual HR, heart rate manually measured on

447 printed ECG tracings.

- 449 **Table 2**
- 450 Differences between smartphone ECG and standard ECG in the evaluation of
- 451 electrocardiographic parameters.
- 452

Parameter	Difference	Range	
Manual HR (bpm)	0	-10; +20	
App HR (bpm)	-3	-31; +20	
P (ms)	0	-20; +0	
P (mV)	-0,1	-0,4; +0,1	
PQ (ms)	0	-20; +20	
QRS (ms)	0	-20; +10	
R (mV)	-0,5	-2,1;+1	

454 Median difference and range are reported.

- 455 App HR, heart rate automatically measured by smartphone application; Manual HR, heart rate
- 456 manually measured on printed ECG tracings.

- **Table 3**
- 459 Agreement between smartphone ECG and standard 6-lead ECG in heart rhythm identification
- 460 in 162 dogs.

	Smartphone ECG				
Standard ECG	S	AF	SV	V	Total
S	138	2	1	0	141
AF	0	12	0	0	12
SV	0	0	2	0	2
V	0	0	0	7	7
Total	138	14	3	7	162

463 AF, atrial fibrillation; S, sinus rhythm; SV, supraventricular rhythm; V, ventricular rhythm.

465	Figure legends
466	
467	Fig. 1. Cranio-caudal orientation of the smartphone in a dog. The camera side of the
468	smartphone was located caudally.
469	
470	Fig. 2. Sinus rhythm with standard ECG (A) and with smartphone ECG (B) in the same dog.
471	Paper speed = 50 mm/s ; $10 \text{ mm} = 1 \text{ mV}$.
472	
473	Fig. 3. Atrial fibrillation with standard ECG (A) and with smartphone ECG (B) in the same
474	dog. Paper speed = 50 mm/s ; $10 \text{ mm} = 1 \text{ mV}$.
475	
476	Fig. 4. Third-degree AVB with standard ECG (A) and with smartphone ECG (B) in the same
477	dog. Paper speed = 50 mm/s ; $5 \text{ mm} = 1 \text{ mV}$.
478	
479	Fig. 5. Pearson test showing a strong positive correlation between the HR values manually
480	measured on standard ECGs and smartphone ECG tracings ($r^2 = 0.99$; P < 0.0001).
481	
482	Fig. 6. Bland-Altman plot showing differences between HR values manually measured on
483	standard ECG and smartphone ECG tracings.
484	
485	Fig. 7. Pearson test showing a strong positive correlation between the HR values manually
486	measured on standard ECGs and HR values produced by the smartphone application ($r^2 =$
487	0.92; P < 0.0001).

- 489 Fig. 8. Bland-Altman plot showing diffences between the HR values manually measured on
- 490 standard ECGs and HR values produced by the smartphone application.