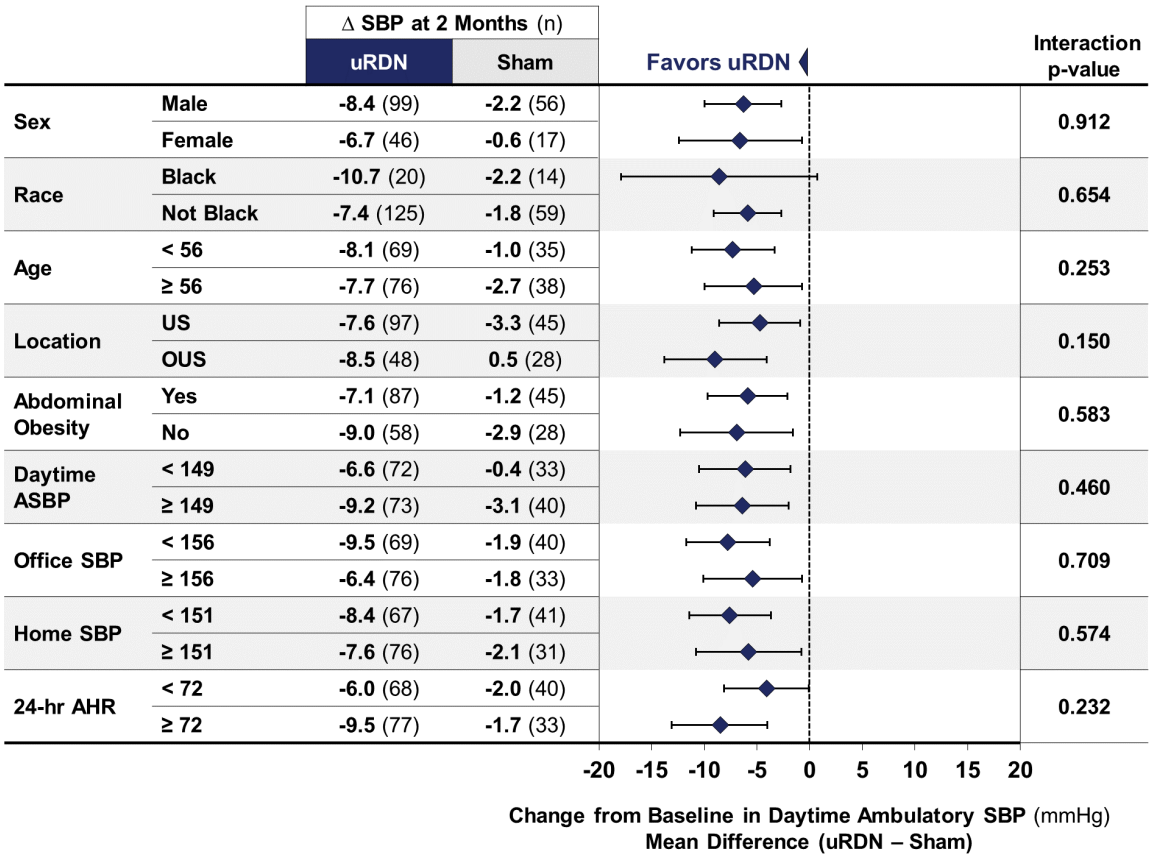
Errata to the Sponsor's Briefing Document
ReCor Medical
Circulatory System Devices Panel
August 22, 2023

Page 77, Figure 33	X-Axis label corrected to mean difference Δ SBP at 2 months corrected to show means N for uRDN Home SBP < 151 corrected to be N=67 N for Sham 24-hr AHR ≥ 72 corrected to be N=33

Figure 33: RADIANCE II: Subgroup Analysis of Primary Efficacy – Mean Changes in Daytime Ambulatory SBP by Patient Characteristics (ITT Population)

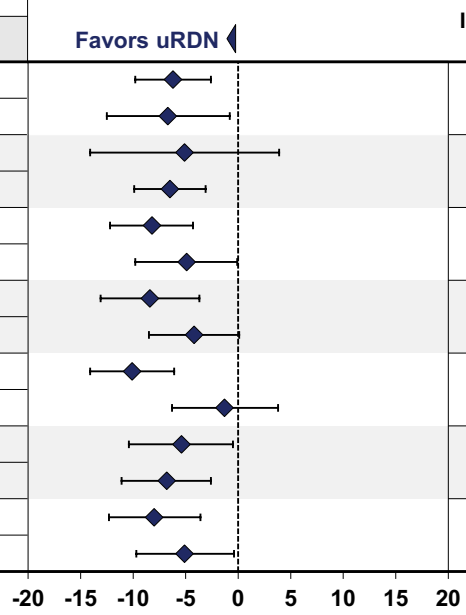


AHR=ambulatory heart rate; OUS=outside United States; SBP=systolic blood pressure; uRDN=ultrasound renal denervation, US=United States

Page 87, Figure 38	Non-Black subgroup: upper 95% CI of mean difference (uRDN – Sham) corrected to -3.1 Age subgroups corrected to < 55 and ≥ 55 Male subgroup: upper 95% CI of mean difference (uRDN – Sham) corrected to -2.6 N for uRDN abdominal obesity corrected to N=41

Figure 38: SOLO: Subgroup Analysis of Primary Efficacy – Mean Changes in Daytime Ambulatory SBP by Patient Characteristics (ITT Population)

		Δ SBP at 2 Months (n)		Interaction p-value
		uRDN	Sham	
Sex	Male	**-7.9** (46)	**-1.7** (39)	**0.659**
	Female	**-9.4** (28)	**-2.8** (33)	
Race	Black	**-7.0** (12)	**-2.2** (13)	**0.813**
	Not Black	**-8.7** (62)	**-2.2** (59)	
Age	< 55	**-9.8** (33)	**-1.7** (35)	**0.328**
	≥ 55	**-7.3** (41)	**-2.6** (37)	
Location	US	**-11.0** (35)	**-2.6** (34)	**0.180**
	OUS	**-6.2** (39)	**-1.8** (38)	
Abdominal Obesity	Yes	**-10.1** (41)	**0.0** (44)	**0.015**
	No	**-6.7** (32)	**-5.6** (28)	
Daytime ASBP	< 150	**-7.2** (39)	**-1.4** (35)	**0.390**
	≥ 150	**-9.9** (35)	**-2.9** (37)	
Office SBP	< 154	**-9.9** (36)	**-1.9** (34)	**0.340**
	≥ 154	**-7.1** (38)	**-2.4** (38)	

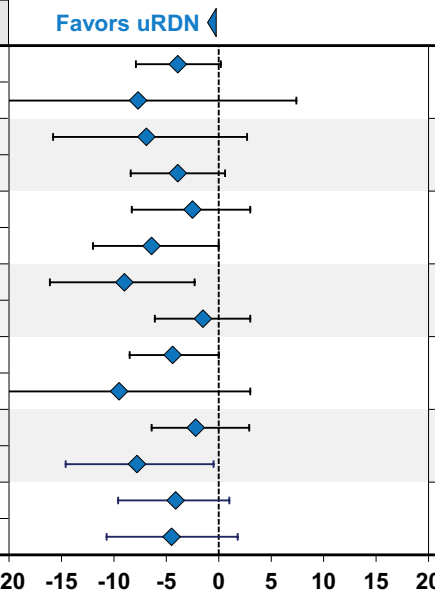


AHR=ambulatory heart rate; OUS=outside United States; SBP=systolic blood pressure; uRDN=ultrasound renal denervation, US=United States

Page 95, Figure 42	Female Δ SBP at 2 months in sham corrected to -1.3

Figure 42: TRIO: Subgroup Analysis of Primary Efficacy – Mean Changes in Daytime Ambulatory SBP by Patient Characteristics (ITT Population)

		Δ SBP at 2 Months (n)		Interaction p-value
		uRDN	Sham	
Sex	Male	-7.4 (56)	-3.3 (53)	0.6294
	Female	-15.2 (13)	-1.3 (14)	
Race	Black	-9.8 (14)	-5.0 (13)	0.7248
	Not Black	-7.4 (55)	-3.0 (54)	
Age	< Median	-8.0 (38)	-5.0 (30)	0.4605
	≥ Median	-8.0 (31)	-1.7 (37)	
Location	US	-10.5 (28)	-3.0 (25)	0.0846
	OUS	-5.9 (41)	-3.1 (42)	
Abdominal Obesity	Yes	-8.7 (54)	-3.6 (55)	0.4115
	No	-10.0 (12)	-0.3 (12)	
Daytime ASBP	< Median	-7.2 (36)	-3.6 (32)	0.2251
	≥ Median	-12.7 (33)	-1.7 (35)	
Office SBP	< Median	-7.3 (33)	-2.5 (32)	0.9702
	≥ Median	-10.1 (36)	-3.9 (35)	



AHR=ambulatory heart rate; OUS=outside United States; SBP=systolic blood pressure; uRDN=ultrasound renal denervation, US=United States