Supplementary materials for "A statistical approach for assessing the compliance of integrated continuous glucose monitoring systems with FDA accuracy requirements"

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Information on datasets

Table S1: Details of the full datasets used

CGM Glucose Range [mg/dL]	<70				70-180				>180				Total			
	n (Sensors)	n (Data points)	Min/Max values per sensor		n (Sensors)	n (Data points)	Min/Max values per sensor		n (Sensors)	n (Data points)	Min/Max values per sensor		n (Sensors)	n (Data points)	Min/Max values per sensor	
Dataset 1	47	470	1	38	48	3796	47	129	48	1669	10	63	48	5935	92	175
Dataset 2	48	468	1	27	48	3277	1	119	47	1611	6	64	48	5356	2	167
Dataset 3	23	234	1	26	24	2531	77	133	24	1224	21	86	24	3989	150	187
Dataset 4	24	380	1	42	24	2237	65	125	24	1002	20	67	24	3619	120	170
Dataset 5	24	182	1	30	24	2639	68	145	24	1012	23	86	24	3833	101	195
Dataset 6	22	180	1	21	23	2470	65	141	23	818	16	69	23	3468	117	175

Table S2: Details of the reduced datasets where the respective data of sensors with only one data point per range were excluded

| CGM Glucose Range [mg/dL]	<70				70-180				>180				Total			
	n (Sensors)	n (Data points)	Min/Max values per sensor		n (Sensors)	n (Data points)	Min/Max values per sensor		n (Sensors)	n (Data points)	Min/Max values per sensor		n (Sensors)	n (Data points)	Min/Max values per sensor	
Dataset 1	46	469	2	38	48	3796	47	129	48	1669	10	63	48	5935	92	175
Dataset 2	45	465	2	27	47	3276	15	119	47	1611	6	64	48	5356	2	167
Dataset 3	21	232	3	26	24	2531	77	133	24	1224	21	86	24	3989	150	187
Dataset 4	21	377	2	42	24	2237	65	125	24	1002	20	67	24	3619	120	170
Dataset 5	22	180	2	30	24	2639	68	145	24	1012	23	86	24	3833	101	195
Dataset 6	20	178	3	21	23	2470	65	141	23	818	16	69	23	3468	117	175

Additional results
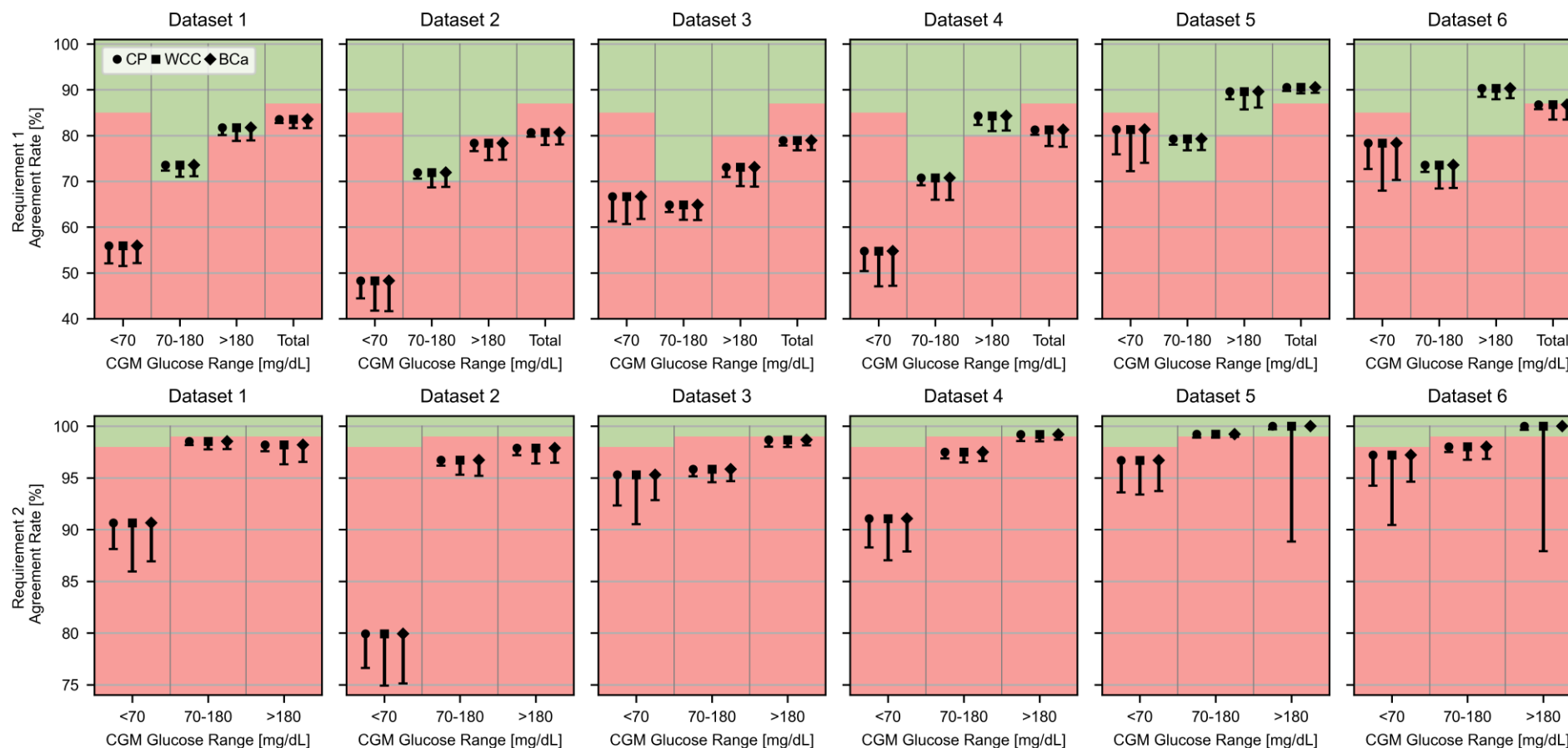
Figure S1: Detailed results of the agreement rates (solid markers) and their lower one-sided 95% confidence bounds (antennae) for all dataset and the three approaches Clopper-Pearson (CP), continuity-corrected Wilson (WCC) and bias-corrected and accelerated bootstrapping (BCa). The background provides the FDA requirements for the lower confidence bounds (red: below, green: above). For requirement 2, datasets 5 and 6 and CGM glucose range >180 mg/dL, the BCa approach yielded no results for the confidence interval due to an agreement rate of 100%.
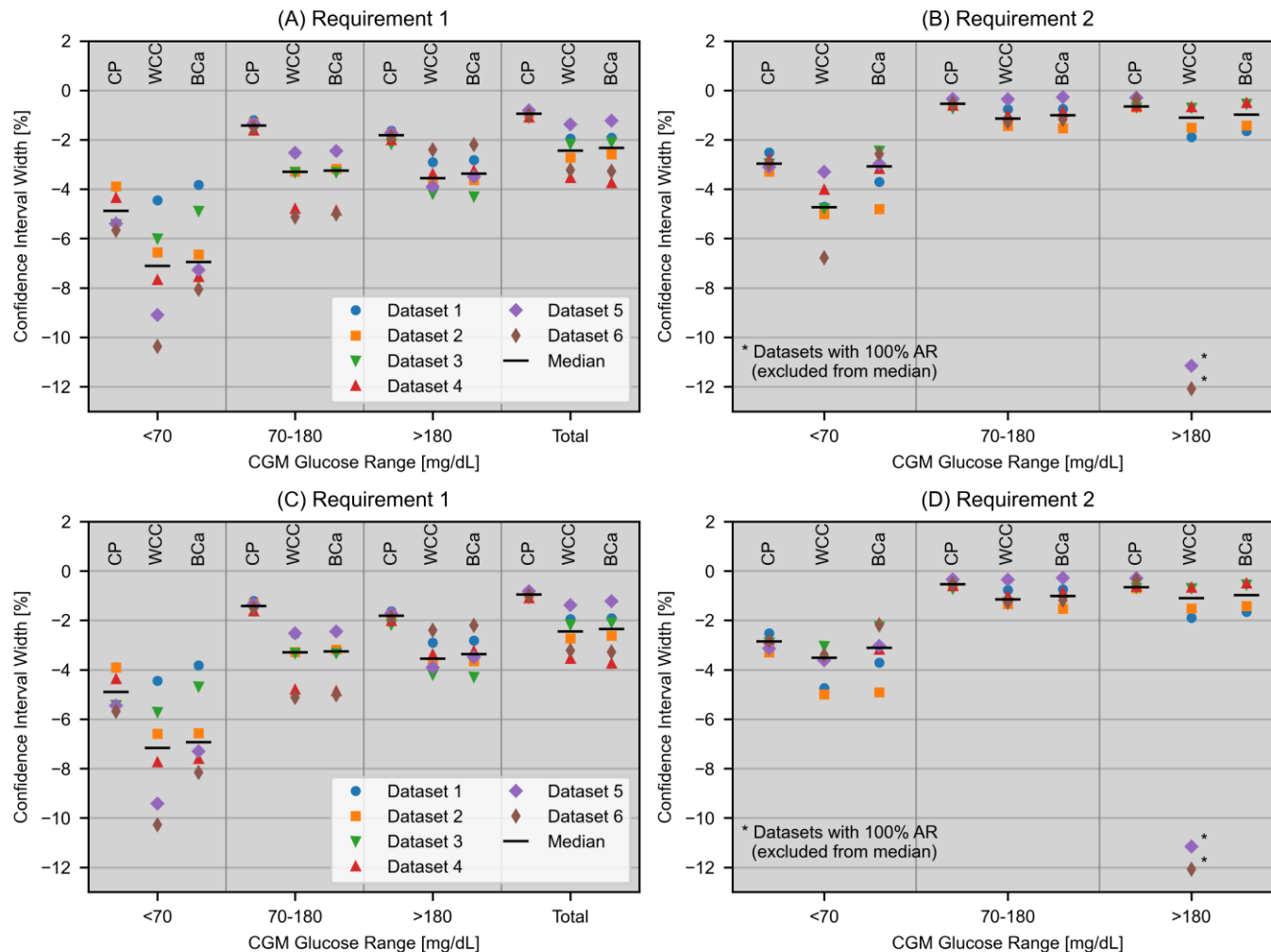
Figure S2: Comparison of results with original (A-B, top) and reduced (C-D, bottom) datasets, where the respective data of sensors with only one data point per range have been removed before the calculation. The results give the confidence interval widths calculated as the difference of the lower bound of the one-sided 95% confidence intervals to the corresponding agreement rate of FDA requirement 1 (A,C) and requirement (B,D). Compared are the results from the Clopper-Pearson (CP), continuity-corrected Wilson (WCC) and bias-corrected and accelerated bootstrapping (BCa) approach for all datasets and separated by CGM glucose ranges.