Methods:

Inclusion Criteria

Each patient had to meet the following criteria to be eligible for the study:

1. Patient was 18 years or older.

2. Patient with ESRD receiving PD therapy, and who was already trained and regularly using the AMIA or HomeChoice APD Cycler with Dianeal PD Solution for at least 12 weeks.

3. Patient was receiving or was willing and able to use Dianeal Low Calcium (2.5 mEq/L) PD prescriptive regimen at study treatment initiation per Investigator's assessment.

4. Patient demonstrated adequate PD therapy with clinical euvolemia as assessed by the Investigator with a total Kt/Vurea of a minimum of 1.7 within 45 days of Screening, or as measured at Screening. If a total Kt/Vurea was not available within 45 days of Screening, it was measured at Screening.

5. Investigator assessed that, with appropriate training, the patient was able to successfully manage his/her dialysis treatment with the SGS.

6. Patient was available and was willing to complete training on the SGS .

7. Patient and home environment were deemed suitable for treatment with the SGS, while in the home.

8. Home electrical and water assessments met the suitability criteria for the SGS.

9. The patient's home had a suitable wireless connection or patient was willing to allow installation of a suitable wireless connection.

10. Patient and/or care partner (if participating) was able to read and understand English and provide informed consent after an explanation of the proposed study. If the patient could not read and understand English, patient could still participate if he/she had a co-residing care partner who could read and understand English, assessed as adequate by the PI.

11. Women of childbearing potential (not menopausal or surgically sterile) could not be pregnant. Serum qualitative and quantitative pregnancy tests were done within 14 days prior to initiation of the study.

- If qualitative serum β-hCG test results were positive, quantitative serum pregnancy test was repeated in 48 hours.

- If quantitative serum β-hCG levels showed clinically significant rise within 48 hours, serum progesterone levels were taken. Serum progesterone > 5 ng/mL excluded a patient from the study.

12. Sexually active males and females had to agree to use a reliable means of contraception during the study and for 30 days afterwards (e.g., oral contraceptive and condom, intrauterine device and condom, or diaphragm with spermicide and condom).

Exclusion Criteria

Patients who met any of the following criteria were excluded from the study:

1. Patients with a history of PD catheter dysfunction within 12 weeks prior to study enrolment, as evaluated by the Investigator.

2. Patients who had episodes of peritonitis or exit site infection within 12 weeks prior to study enrolment.

3. Patients who had signs of impending or current infection, including a cloudy dialysis effluent or a dialysis white cell count > 100 µL or > 0.1 x 109/L (after a dwell time of at least 2 hours), with > 50% polymorphonuclear cells (PMNs), and/or positive dialysis effluent culture.

4. Patients who had a severe primary immune deficiency or other condition that may have masked clinical signs of peritonitis, as evaluated by the Investigator.

5. Patients with a history of repeated non-compliance with PD, therapy (e.g., a substantial number of missed clinic visits, missed treatments, or a history of mismanagement of diet or medications), as evaluated by the Investigator.

6. Patients who had acute renal failure with the chance of recovery.

7. Patients who were pre-scheduled for a living donor kidney transplant within the following 6 months.

8. Patients who were not expected to live at least 6 months while maintaining PD treatment.

9. Patients who had major abdominal surgery within 6 months prior to study enrolment.

10. Patients who had a current abdominal hernia, as evaluated by the Investigator.

11. Patients with advanced liver or pulmonary disease, as evaluated by the Investigator.

12. Patients with a positive serology test result for Hepatitis B Virus or Hepatitis C Virus infection, or aspartate transaminase or alanine aminotransferase > 3 x the upper limit of normal at Screening.7

13. Patients with diagnosed stage III or IV New York Heart Association (NYHA) heart failure.

14. Patients who had an active malignancy. (Cancers determined to be cured or in remission for ≥ 1 year, curatively resected basal cell or squamous skin cell cancers, cervical cancer in situ, or resected colonic polyps were acceptable diagnosis).

15. Patients with a history of a clinically significant illness and/or clinically significant surgery within the previous 14 days preceding the Screening Visit, as determined by the Investigator.

16. Patients who were enrolled in another interventional clinical study.

There were 12 sites for the study which included- University of Mississippi Medical Center, Mississippi; Mayo Clinic- Jacksonville, Florida; Mount Sinai Hospital- New York, NY; The Rogosin Institute- New York, NY; Medical District Home Dialysis, LLC, Illinois; St. Bernards Medical Center, Arkansas; Scott & White Memorial Hospital (Baylor-Temple), Texas; Satellite WellBound San Mateo, California; University of

Michigan, Michigan; Satellite WellBound San Jose, California; Satellite WellBound Mountain View, California; and Desoto Regional Dialysis Center, LLC (ARA), Texas. Prior to the start of the study, IRB approvals were received from all central and local IRBs as appropriate for the various participating institutions and clinics. Three sites used local IRBs, and the remainder used a central IRB (Baylor Scott & White: #019-127; Mayo Clinic: #18-010824; Mount Sinai Hospital: IRB-MSH#19-10; and Advarra: Pro00029241).

During the Screening Period, all consenting patients had a home assessment, including feed (tap) water analysis, to confirm their home environment was suitable for this study. Data was collected throughout the duration of the 12 week study period, including the Screening Period, Baseline Period (In-center Training Period), Study Treatment Period, Follow-up Period, and the End-of-Study Visit/Early Termination Visit. All AEs (not reported as medical history), product complaints (PCs), and device deficiencies (DDs) observed by the study personnel or reported by the patient during the course of the study were documented from the time of signing the Informed consent form through the End-of-Study/Early Termination Visit. The PI or designee (e.g., sub-Investigator) assessed each patient at the Screening Visit and on a weekly basis, according to standard of care, which included evaluation of blood pressure (BP), pulse rate, weight, fluid status, and dialysis prescription. Laboratory data was collected at Screening and during the use of the AMIA APD Solution Generation System.

Statistical Methods:

The Study was based on the Intent-to-Treat principle and included all patients who received at least one treatment with the AMIA APD Solution Generation System and who had at least one measurement for the primary endpoint. A formal sample size calculation was not performed. Up to 50 patients were planned to be enrolled such that a total target of 30 evaluable patients were to complete the 12-week Study Treatment Period and the Follow-up Period.

The chemical composition of the final dialysis solution produced by the AMIA APD Solution Generation System, during simulated treatment at visits 1, 2, 3, and 4, was tested and compared to the specifications of Baxter's approved Dianeal Low Calcium (2.5 mEq/L) PD Solution. PD adequacy was measured by sample collection and calculation of Total Kt/Vurea (dialysate Kt/Vurea plus renal Kt/Vurea) occurring one time during Week 5, 6, 7, or 8 of the Study Treatment Period.

Product water from the WD was collected at Visits 1, 2, 3, and 4 and tested for microbiological (including endotoxin) contamination per ISO standard. Microbiological Testing of the Product Water from the Holding Bag was collected at Visits 1, 2, 3, and 4 and tested for microbiological contamination and endotoxin levels per ISO standards.

The safety profile of the AMIA APD SGS was assessed by collecting AEs, SAEs, ADEs, SADEs, incidence of device alarms, and vital signs. Adverse events and SAEs were to be collected from the time of signing informed consent throughout the Study Treatment Period and during the follow-up period of 5 to 10 days after the last study treatment. Vital signs were to be recorded on the electronic case report form at Screening, Study Visit 2, Study Visit 3, Study Visit 4, and at the End-of-Study Visit.

Table S1: Demographics and baseline characteristics of enrolled patients

Characteristics	Category/Value	Total (N=22) n (%)
Sex	Female	14 (63.6)
	Male	8 (36.4)
Race	Asian	5 (22.7)
	Black or African American	7 (31.8)
	White	9 (40.9)
	Other	1 (4.5)
Ethnic Group	Hispanic or Latino	2 (9.1)
	Not Hispanic or Latino	20 (90.9)
Primary Renal Diagnosis Etiology	Diabetic Nephropathy	8 (36.4)
	Hypertensive Nephropathy	4 (18.2)
	Glomerulonephritis	1 (4.5)
	Obstructive Uropathy	1 (4.5)
	Polycystic Kidney Disease	1 (4.5)
	Autoimmune Disease (includes lupus)	2 (9.1)
	Immunoglobulin A (IgA)	1 (4.5)
	Other	4 (18.2)
Did the patient have a care partner?	No	15 (68.2)
	Yes	7 (31.8)

Table S2: Composition of Amia APD generated solutions

Component	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
Dextrose	75.5	126	214
Sodium	132	132	132
Calcium	1.25	1.25	1.25
Magnesium	0.25	0.25	0.25
Chloride	95	95	95
Lactate	40	40	40
pH	~6	~6	~6

Table S3: Individual Parameter Testing of the Chemical Composition of the Dialysis Solution

Parameter	Total Tests[1]	Mean (SD)	Median	Min, Max
$CaCl_2$ $2H_2O$ (g/L)	69	0.185 (0.0044)	0.184	0.178, 0.207
Chloride (g/L)	69	5.535 (0.0240)	5.540	5.48, 5.6
$MgCl_2$ $6H_2O$ (g/L)	69	0.052 (0.0008)	0.052	0.049, 0.054
pH at 25°C	69	6.23 (0.122)	6.20	6, 6.5
Sodium Lactate (g/L)	69	4.458 (0.0407)	4.450	4.39, 4.56
5-HMF	67	0.024 (0.0153)	0.020	0.02, 0.14
Color	67	4.0 (1.67)	4.0	0, 7
Sodium (mEq/L)	67	131.5 (1.55)	131.0	128, 136
Dextrose Hydrous Assay	66	2.376 (1.0822)	1.540	1.5, 4.3

5-HMF = 5-hydroxymethylfurfural; $CaCl_2$ $2H_2O$ = calcium chloride dihydrate; max = maximum; $MgCl_2$ $6H_2O$ = magnesium chloride hexahydrate; min = minimum; SD = standard deviation

[1] The total number of tests excludes those tests with a missing result

Table S4: Individual Parameter Summary of Microbiological and Chemical Testing of the Product Water from the Water Device

Parameter (unit)	Total Tests[1]	Mean (SD)	Median	Min, Max
Endotoxin (EU/mL)	68	0.026 (0.0648)	0.010	0.005, 0.45
TAMC (CFU/mL)	63	1.7 (4.26)	0.0	0, 28
TYMC (CFU/mL)	63	0.8 (2.58)	0.0	0, 18
Fluoride (g/mL)	51	0.059 (0.0774)	0.034	0.034, 0.48
Aluminum (g/mL)	53	0.007 (0.0015)	0.007	0.0072, 0.018
Cadmium (g/mL)	53	0.000 (0.0004)	0.000	0.00012, 0.0019
Chlorine (g/mL)	53	0.101 (0.0041)	0.100	0.1, 0.13
Cobalt (g/mL)	53	0.001 (0.0009)	0.001	0.0005, 0.0046
Sodium (g/mL)	53	4.566 (11.7888)	1.700	0.59, 71.6
Antimony (g/mL)	53	0.001 (0.0000)	0.001	0.0005, 0.00057
Arsenic (g/mL)	53	0.001 (0.0001)	0.001	0.0005, 0.001
Barium (g/mL)	53	0.001 (0.0008)	0.001	0.0005, 0.0037
Beryllium (g/mL)	53	0.000 (0.00)	0.000	0.00007, 0.00008
Calcium (g/mL)	53	0.218 (0.1110)	0.200	0.2, 1
Chromium (g/mL)	53	0.001 (0.0002)	0.001	0.0005, 0.0016
Copper (g/mL)	53	0.002 (0.0093)	0.001	0.00093, 0.069
Lead (g/mL)	53	0.001 (0.0000)	0.001	0.00064, 0.00072
Magnesium (g/mL)	53	0.166 (0.0342)	0.160	0.16, 0.39
Mercury (g/mL)	53	0.000 (0.0000)	0.000	0.0001, 0.0001
Nickel (g/mL)	53	0.001 (0.0007)	0.001	0.00062, 0.0039
Nitrate (g/mL)	53	0.029 (0.0241)	0.025	0.025, 0.2
Potassium (g/mL)	53	0.274 (0.0275)	0.270	0.27, 0.47
Selenium (g/mL)	53	0.001 (0.0000)	0.001	0.00083, 0.00094
Silver (g/mL)	53	0.000 (0.0007)	0.000	0.00005, 0.003
Sulfate (g/mL)	53	2.50 (0.000)	2.50	2.5, 2.5
Thallium (g/mL)	53	0.001 (0.0000)	0.001	0.0005, 0.00057
Zinc (g/mL)	53	0.007 (0.0055)	0.004	0.0043, 0.031

Max = maximum; min = minimum; SD = standard deviation

[1] The total number of tests excludes those tests with a missing result

Table S5: Secondary efficacy Endpoint: Total Kt/Vurea Summary

Visit	Variable	Test Values	Change from Baseline
Screening Visit (Baseline Value)	N	26	N/A
	Mean (SD)	2.42 (0.630)	
	Median	2.25	
	Minimum, Maximum	1.7, 3.9	
Total Kt/V_{urea} Visit	N	15	15
	Mean (SD)	2.13 (0.439)	-0.15 (0.370)
	Median	2.10	-0.10
	Minimum, Maximum	1.5, 3.2	-1, 0.3

N/A = not applicable; SD = standard deviation
n = number of results available

Table S6: Summary of Device Deficiency Characteristics

Characteristics[1]	Category	N°. of Patients n (%)[2]	N°. of Events n (%)[3]	N°. of Events per Total Device Days
Total DDs		20	96	
Product	Amia APD Cycler (PoC Version)	14 (70.0)	23 (24.0)	0.0112
	Amia APD Solution Generation System Set	5 (25.0)	6 (6.3)	0.0029
	Water Device	13 (65.0)	35 (36.5)	0.0170
	Sharesource Connectivity Platform	1 (5.0)	1 (1.0)	0.0005
	Filter Pack	1 (5.0)	2 (2.1)	0.0010
	1L Dextrose Concentrate	1 (5.0)	1 (1.0)	0.0005
	1L Electrolyte Concentrate	3 (15.0)	4 (4.2)	0.0019
	Universal Ion Exchanger USM-818	3 (15.0)	3 (3.1)	0.0015
	WIFI Bridge	3 (15.0)	4 (4.2)	0.0019
	Water Softener	5 (25.0)	8 (8.3)	0.0039
	Other	7 (35.0)	9 (9.4)	0.0044
Type of DD	Product issue/Device Failure	11 (55.0)	23 (24.0)	0.0112
	Product issue/Device Malfunction	19 (95.0)	73 (76.0)	0.0355
Occurrence of DD	Before Treatment	19 (95.0)	54 (56.3)	0.0263
	During Treatment	11 (55.0)	25 (26.0)	0.0122
	After Treatment	9 (45.0)	17 (17.7)	0.0083
Did the device give an alert, alarm, or error message?	No	15 (75.0)	36 (37.5)	
	Alarm	6 (30.0)	14 (14.6)	0.0068
	Alert	11 (55.0)	19 (19.8)	0.0093
	Error message	11 (55.0)	27 (28.1)	0.0131
Was there a safety concern?	No	16 (80.0)	91 (94.8)	
	Yes	4 (20.0)	5 (5.2)	0.0024
Did the DD result in an AE/SUSAR/UADE?	No	20 (100.0)	96 (100.0)	

AE = adverse event; DD = device deficiency; SUSAR = suspected unexpected serious adverse reaction; UADE = unexpected adverse device effect

[1] Number of patients is the number of patients with at least one event in that particular category

[2] Percentage in the patients column is based on the number of patients with at least 1 DD

[3] Percentage in the events column is the percentage of overall events

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Feasibility discussed in main text as a "proof of concept", can be added to title at reviewers/editors discretion
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3, 8
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A (no important changes)
Participants	4a	Eligibility criteria for participants	Supplementary File
	4b	Settings and locations where the data were collected	4, 5
	4c	How participants were identified and consented	Supplementary File
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	N/A (technical feasibility of prototype development, not available to the public)

Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Supplementary File
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A (no important changes)
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	N/A, intervention development
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A, none
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A, non-randomized study
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A, non-randomized study
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A, non-randomized study
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A, non-randomized study
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A, open-label study
	11b	If relevant, description of the similarity of interventions	N/A, single-arm study
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Supplementary File
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Supplementary File, Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	*Added to 5*
	14b	Why the pilot trial ended or was stopped	5

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Supplementary File (Table S1)
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	5, 6, Supplementary File
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	5, 6, Supplementary File
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	6, Supplementary File
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	7
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	7
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	7
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	8
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	N/A, device feasibility study/investigational new drug; Registered with US FDA IND#141130 (not a trial registry), added to page 4
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A, not separately published
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Addressed in COI Disclosures

	26	Ethical approval or approval by research review committee, confirmed with reference number	Added IRB approval language to page 4, TBD-need the IRB approval numbers

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.