Title Page

Clinical Investigational Plan (CIP) INFORMATION	
Title:	Optimizing the Preparation Regime Prior to Colonoscopy Procedure with Pure-Vu System
CIP Number:	**CL00042**
Version Date:	December 13, 2017
Revision:	1.0
Sponsor:	Motus GI Medical Technologies LTD. Address: Keren Hayesod 22, Tirat Carmel, ZIP 3902638, Israel Tel: +972-4-6214446 Fax: +972-4-6214442

Summary of Changes to CIP			
Revision	**Section**	**Description of Change**	**Reason for Change**
NA	NA	NA	NA

1.0 Signature Page

Principal Investigator Signature Page

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I, the undersigned, have read and understood the protocol specified above and agree on its content. I agree to perform and conduct the study as described in the protocol and in accordance with the relevant laws/regulations and standards outlined in the Clinical Trial Agreement.

_____ _____ _____

Name Signature Date

Sponsor representative signature

_____ _____ _____

Name Signature Date

2.0 Table of Contents

3.0 Protocol Synopsis

Study Summary		
Study Purpose	To determine the optimal bowel preparation regimen for Pure-Vu System procedures in patients indicate for colonoscopy procedure.	
Objective	The primary objective of this multicenter, prospective, randomized study is to evaluate the performance of Pure-Vu System in cleansing patients' colon who are indicated for a colonoscopy procedure using one of two different reduce bowel preparation regimes.in addition, the cecum intubation rate, time to cecum, total procedure time, and adverse event will be evaluated.	
Test and Comparator Procedures	**Prep A**	**Prep B**
	5 days prior procedure day	
	No seedy food	
	1 day prior procedure day	
	Low residue diet;	
	Spilt dose of 15 oz Magnesium Citrate + 39 oz of clear liquid	**Spilt dose of 10 oz Magnesium Citrate + 32oz of clear liquid**
	Procedure Day	
	Clear-liquid diet up to 3 hours prior to the procedure	
	Fasting (no food / liquids) start 3 hours prior to procedure time	
	***At least 2 liter water per day during the preparation days.**	

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Study Sponsor	Motus GI Medical Technologies, Keren Hayesod 22, Tirat Carmel, ZIP 3902638, Israel Tel: +972 (4) 6214446/103 Fax: +972 (4) 6214442
Sponsor Representative	Ravit Peled Director of Clinical Affairs
Study Type	**Multicenter, prospective, randomized feasibility study**
Study Product	Pure-Vu System
Study Phase	Post-market
IDE Number	K173392 Class II
Study Location	United States
Study Duration	Study period will last approx. 12 months
Study Design	Patients will be randomized to receive one of two bowel preparation regimens prior to colonoscopy with Pure-Vu procedure.
Planned Follow-Up	Telephone follow-up will be conducted at 2-3 working days post-procedure to assess subject well-being and capture any adverse events.
Subject Population	Subjects indicate for colonoscopy procedure

Planned # of Subjects	Up to 100 subjects
Planned # of Sites	Up to 3 clinical sites
Primary Endpoint	The rate of adequate cleansing level per patient will be evaluated by the BBPS(1) scoring index post the cleansing operation in both study arms.
Secondary Outcomes	The following secondary outcomes will be determined : • Adverse events • Cecal intubation rate • Time to Cecum • Total procedure time
Randomization	Block randomization will be employed for each site to assign subjects to one of the two bowel preparation arms (Prep A versus Prep B).
Eligibility Criteria	**Inclusion Criteria** 1. Subjects scheduled for colonoscopy procedure 2. Subjects in the age range 22-7 5 years inclusive 3. Subject is willing and able to participate in the study procedures and to understand and sign the informed consent. **Exclusion Criteria** 1. Patients with active Inflammatory Bowel Disease 2. Patients with known diverticulitis disease or with prior incomplete colonoscopy due to diverticular disease 3. Patients with known bowel obstruction 4. Patient with chronic constipation 5. History of prior surgery to colon and/or rectum

	6. ASA ≥ III 7. Renal insufficiency (Creatinine ≥ 1.5mg /dL) (based on medical history) 8. Abnormal Liver enzymes (ALT/AST ≥ 2 times upper limits of normal) (based on medical history) 9. Patients taking anticoagulants drugs (excluding aspirin) or dual antiplatelet therapy 10. Patients with known coagulation disorder (INR >1.5). 11. Pregnancy (as stated by patient) or breast feeding 12. Patients with altered mental status/inability to provide informed consent
Statistics	
Primary Endpoint Analysis	The primary endpoint is the rate of adequate bowel cleansing level, as determined by Boston Bowel Preparation Scale (BBPS), assessed per patient in both study arms. Chi-square or Fisher's exact test, as appropriate, will be performed in order to compare the proportions of good or excellent cleansing level (i.e., BBPS>1 in all colon segments) post cleansing procedure between the two study arms.
Secondary Analyses	**Cecum intubation rate** Proportion tests (Chi-square or Fisher's exact) will be performed in order to compare between the two preparation procedures cecum intubation rate **Time analysis** T-tests for continuous variables will be performed in order to evaluated the difference between Prep A and Prep B for the following: • Total procedure time

	• Time to cecum **Safety analysis** Individual listings of adverse events including type of device, adverse events (reported term) start date, duration, and severity will be provided.
Determination of Sample Size	This is a pilot study that will include up to 100 patients; no statistical considerations were made to determine the sample size.
Interim analyses	No Interim analysis is planned.

4.0 Acronyms and Definitions

ADE	adverse device effect
ADL	activities of daily living
AE	adverse event
CRF	case report form
FDA	Food and Drug Administration
GCP	good clinical practice
GI	gastrointestinal
ICF	informed consent form
IFU	Instruction for use
ICH	International Conference on Harmonisation
IRB	institutional review board
ISO	International Organization for Standardization
OC	optical colonoscopy
DCBE	double contrast barium enema
CT	computed tomography

MagC	Magnesium Citrate
SAE	serious adverse event
SADE	serious adverse device effect
USADE	unanticipated serious adverse device effect
WS	Workstation
WSC	Workstation Connector
BBPS	Boston Bowel Preparation Scale

5.0 Introduction

This document is a protocol for human research study. This study will be conducted in accordance with US government regulation, and applicable international standard of Good Clinical Practice, and institutional research policies and procedures.

5.1 Background

Colorectal cancer is the third most common cancer in men and the second most common cancer in women worldwide (2). In the United States, approximately 134,490 new cases are estimated for 2016 with approximately 49,190 deaths (8.0% of all cancer deaths) (3). Because colorectal cancer tends to develop slowly, screening and early detection can significantly reduce both the incidence and associated mortality of the disease (4).

Methods for the evaluation of subjects with suspected colonic disease include optical colonoscopy (OC) and radiologic imaging such as double contrast barium enema (DCBE) or computed tomography (CT) colonoscopy (5). While OC is considered the gold standard, patient acceptance rates are low due to perceived discomfort.

A key factor for ensuring high quality colonoscopy and successful screening is good colon preparation. Bowel preparation prior to colonoscopy is one of the major barriers to patient compliance in screening colonoscopy estimated as many as 38% of patients do not complete the bowel preparation due to palatability and/or intolerance to the large volume. Inadequate preparation is a major obstacle for achieving a high-quality colonoscopy (6). Poor bowel preparation prolongs overall screening and procedure time, decreases cecal intubation rates,

reduces the detection of colorectal neoplasms, increases complication rates and leads to return visits for screening which in turn leads to increased costs (7-12)

Despite the importance of good preparation, up to 25% of patients arrive for colonoscopy with inadequate bowel preparation (13) .

Pure-Vu System enables colon cleansing during standard colonoscopy using a standard colonoscope with a length of 1630mm – 1710mm and a diameter between 12.8mm – 13.7mm The Oversleeve device, which fits over the colonoscope and is connected to an external workstation, generates fluid jets to break up the feces. The fecal matter & fluids are removed through the evacuation channels of the Oversleeve device into an external waste receptacle.

The current study is designed to evaluate the efficacy of two different reduced preparation regimen intended for use with Pure-Vu System. The study objectives are to compare cleansing levels, cecum intubation rate, the time to cecum, the total procedure time, and adverse event (AE) rates following use of the two different bowel preparation methods in subjects undergoing standard colonoscopy.

6.0 Investigational Device

6.1 General Description

The Pure-Vu System is Food and Drug Administration (FDA) approved device since September 22, 2016, intended to connect to standard colonoscopes to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter, e.g. blood.

The Pure-Vu System comprises the following components:

- The Pure-Vu Workstation (WS) - controls the flow of gas (e.g. air) and water or saline to the Oversleeve device and the evacuation of fecal matter and fluids out of the body.
- The disposable Oversleeve is mounted on top of the colonoscope allowing the physician to clean the colon. The Oversleeve is connected to WS via the WS Connector (WSC).
- The disposable WS Connector is mounted onto the front panel of the WS and connects to the irrigation and sensing lines of the Oversleeve.

- The loading fixture is an ancillary device that is used to aid the nurse in loading the device on the colonoscope.
- External reservoir for collecting the evacuated fecal matter and fluids
- External foot pedals that operate the cleansing and evacuation process to be used by the investigator.

Below is a drawing showing the various components of the system and where they connect to each other.

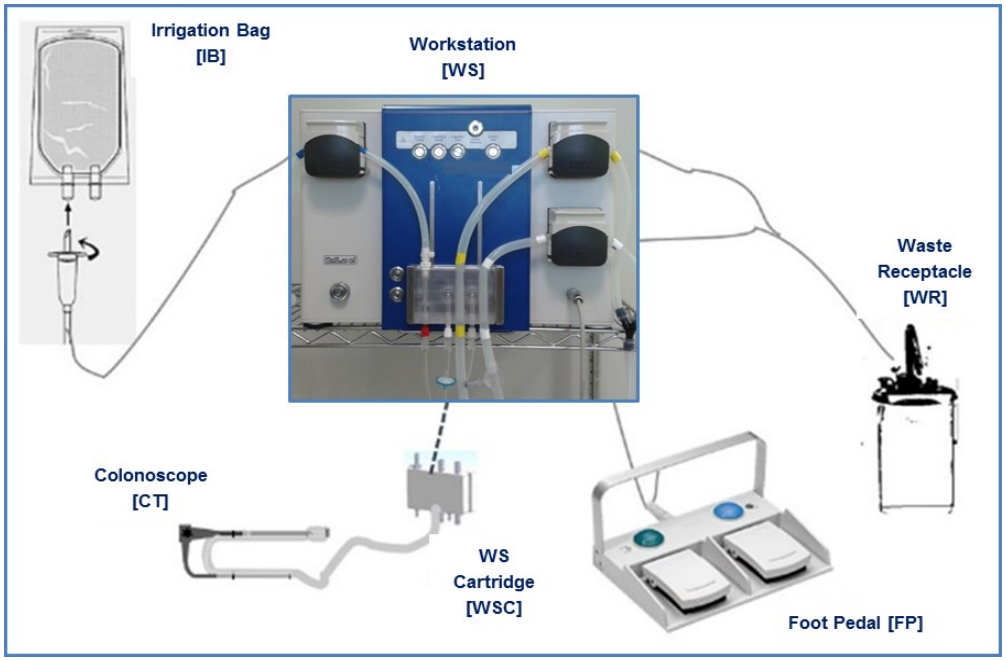


Figure 1: Pure-Vu Workstation – General design & components

A detailed description of the system components, its principles of operation, dimensions and packaging is elaborated in the Instruction for use (IFU).

6.1.1 Work Station (WS)

The WS controls the flow of gas (e.g. air) and water or saline to the Oversleeve device and the evacuation of fecal matter and fluids out of the body. The WS has four main functions:

- Cleansing: Creates an irrigation stream, which is a mixture of liquid (water or saline) and air into the colon to break up fecal matter. The irrigation of air and liquid (water or saline) is referred to as "cleansing jets". The cleansing has three modes, high, medium and low with medium being the default setting. The physician can operate the system as per his clinical judgment. It is important to note that the evacuation function noted below is active during cleansing so that fluid is input and removed from the colon simultaneously.
- Evacuation: Removes fecal matter and fluids out of the colon. The evacuation function is active during the cleansing as previously noted and can also be used independently. During evacuation the system senses the pressure in the evacuation channel of the Oversleeve and if the pressure goes below pre-set limits will automatically reverse the flow to purge a potential blockage and then switch back to continue evacuation. The user also has the ability to manually purge the evacuation channel as well.
- User interface: Consists of actuators and indicators on the WS itself as well as a foot pedal to activate the main functions of the system so that users' hands are free to manipulate the colonoscope in a standard fashion.

Oversleeve The Oversleeve is mounted on top of the colonoscope and is connected to WS via the WS Connector. The Add-on includes the following main components:

- Tubing: Six (6) tubes (2 Pebax and 4 PVC) that support the irrigation, evacuation and sensing functions of the system.
- Cleansing and Evacuation head: The Oversleeve's distal part which contains irrigation ports, evacuation openings, and colon sensing port.

- Inner sleeve: This sleeve attaches the Oversleeve to the colonoscope along its length. This sleeve is inflated to allow the colonoscope to be inserted through it and then deflated to hold onto the colonoscope when it is navigated through the colon. The inner sleeve is also attached to the outer sleeve noted below on one side.
- Outer sleeve: This sleeve covers the entire portion of the device that goes inside the colon keeping the tubes in position and providing a smooth surface to interface with the wall of the colon. The distal 28 cm of the sleeve is coated with hydrophilic coating to provide a lubricious surface to aid in advancing the system through the colon.
- Inflation connector: Provides the port to pressurize the inner sleeve during the loading of the colonoscope and provides the entry location for the colonoscope to be inserted into the Oversleeve.

6.1.2 WS Connector

The disposable WS Connector is mounted onto the front panel of the WS and connects to the irrigation and sensing lines of the Oversleeve.

The WS Connector is slide into the groves on the WS and once in place the user activates the locking mechanism to hold the WS Connector in place and align the connections to the two sensors and the air source for the irrigation. The user will then place the tubing that is on the proximal side of the WS Connector into for irrigation. The evacuation tubing will form the Oversleeve will be placed into the channels on the WS Connector and then into the pump heads according to its color-coding. Last the user will connect a standard bag of saline or water to the irrigation line and the evacuation line to the recommended waste tank.

6.1.3 Ancillary Apparatus

The final part of the system are ancillary apparatus to aid the nurse in loading the device on a colonoscope.

- The loading apparatus consists of a pressure source and a distal sealing plug to facilitate inflation of the inner sleeve of the device as well as a base to keep the Oversleeve in a stable position to allow insertion of the colonoscope through the inner sleeve.

6.2 Pre-clinical data

The Pure-Vu system was used by four experienced gastroenterologists in 35 Yorkshire cross swine (66% female) that received a reduced bowel preparation to ensure an inadequate bowel preparation at baseline. Prior to the colonoscopy the Pure-Vu was attached to the colonoscope and the baseline prep was assessed during insertion. The Pure-Vu system was then employed to cleanse the colon and the prep was then assessed post-Pure-Vu use.

No adverse effects and no failed or prematurely terminated cases were noted. Fourteen percent of the swine colons were adequately prepped at baseline (mean BBPS score 0.5 ± 0.7) and improved to 100% after use of Pure-Vu ($p < 0.001$) (mean BBPS score 3.0 ± 0.0). The physicians found Pure-Vu easy and intuitive to operate.

The Pure-Vu system effectively cleaned inadequately prepped swine colons and proved to be easy to use.

6.3 Clinical data to Date

The latest Pure-Vu System tested in ninety-seven subjects (54% males) from five sites using similar protocol.

Pure-Vu was used in subjects with a partially prepped receiving a colonoscopy for screening, diagnostic or surveillance.

To ensure an inadequately prepped colon subjects underwent a reduced preparation consisting of dietary restrictions (no dried fruit, seeds or nuts) starting 2 days prior to the colonoscopy, an 18 to 24 hour clear liquid diet and a split dose of 20mg Bisacodyl.

The cleansing quality was evaluated before and after use of the Pure-Vu System with the Boston Bowel Preparation Score (BBPS) (1).

Two patients were excluded from the analysis due to the followings:

- One patient who had breakfast on day of procedure was excluded from the cleansing efficacy and usability analysis due to non-compliance with the pre-procedural prep regimen.
- In one patients the device could not reach beyond the sigmoid colon due to the patient's anatomy, thus the physician used a slim colonoscope to complete the procedure and indicated that only a slim colonoscope would be able to advance past the sigmoid and into the cecum.

The Pure-Vu significantly increased the number of subjects with an adequate cleansing level (BBPS >= 2 for all 3 colon segments) from 25%; CI 95% [17%, 35%] at baseline to 99%; CI 95% [94%, 100%] after Pure-Vu. Cecum intubation rate was 98%; CI 95% [94%, 100%]). Mean post-treatment BBPS score was 8.7 ± 1.0 vs. 3.9 ± 2.2 prior to Pure-Vu use. Physicians were satisfied with the device's use. No major difficulties were experienced when performing polypectomy and no serious adverse events were reported.

7.0 Risk/Benefit Analysis

7.1 Anticipated Risks Associated with Pure-Vu System conjunction with a standard colonoscope

The Pure-Vu is used in conjunction with a standard colonoscope during a colonoscopy procedure. Hence, the complications associated with using the Pure-Vu are anticipated to be similar to those associated with the colonoscopy procedure. As with any colonoscopy procedure, when using the Pure-Vu there is some risk of bowel perforation, pain, infection and bleeding. Although the risks of the procedure with the Pure-Vu System are expected to be comparable to conventional colonoscope (0.35%), the device is an Oversleeve to a standard colonoscope. Hence, diameter is bigger, and the cleansing time may add some minutes to the procedure time.

a potential risks associated with the participation in the clinical investigation may include a repeated colonoscopy procedure as the subjects enrolled to the study are required to undergo a limited prep as compared to the preparation given prior to standard colonoscopy procedure.

The latest Pure-Vu version was tested in an animal study including 35 pigs and in preliminary clinical studies including 97 subjects.

No major complication or serious adverse events occurred within the course of those studies.

In addition, these clinical studies demonstrated an excellent cleansing effectiveness; Pure-Vu improved the cleansing level from 25% at baseline to 99% after the cleansing was operated and in 98% of the patients the cecum was reached and the procedures completed successfully. Efficacy results support the study design rationale that decreases the risks associated with the preparation without increasing the risk related to incomplete/ repeated colonoscopy procedure.

Lastly, patients to be enrolled to this study shall be eligible to colonoscopy, thus the risks detailed above covers all the population intended to participate in the study.

Considering the residual risks and the potential and the risk against benefit assessment, it can be concluded that the system may offer potential benefit to the patients along with no significant risk increase.

7.2 Anticipated Risks Associated with bowel preparation agents

The Bowel preparation agent used in this study are approved in U.S.

The main anticipated risks associated with the bowel preparation agents including nausea with or without vomiting, abdominal pain and dehydration.

The preparation in this study is less intensive compared to the standard preparation done prior to colonoscopy procedure, thus we expect that the risks related to the preparation agent will be similar or even lower than the risks following a standard preparation to colonoscopy procedure.

Reduction of the bowel preparation regimen will minimize patient discomfort and AEs associated with bowel cleansing, and potentially maximize the efficacy of the colonoscopy procedure with Pure-Vu System.

7.3 Residual risk associated with the investigational device

The residual risk is the risk remaining after the risk controls have been implemented.

The residual risk is evaluated according to the following:

- Acceptable Residual risk includes all RPN ≤ 9.
- Risks rated 10-16 will be acceptable if the risk benefit ratio justifies it.

All risks of using Pure-Vu were mitigated by risk management process according to EN ISO 14971:2012.

The mitigation to the risks associated with the investigational device includes but is not limited to the followings:

- Smooth head shape that contains lumens for cleansing jets and evacuation. The lumens' size were optimized to ensure the safety of the patients along with effective cleansing.
- The Pure-Vu Oversleeve are made from a flexible and low friction material to allow ease advancement through the colon and to minimize any impact to the steering angle of the colonoscope.
- Hydrophilic coating at the distal 30cm of the outer sleeve to create a lubricious surface to allow ease insertion and advancement.
- Cleansing procedure can be operated in 3 modes (low, medium, high), where the physician can control the intensity of cleansing jets to ensure the safety of the patients along with effective cleansing.

The potential residual risk following the mitigations are all acceptable (for more details please refer to "Risk analysis report").

7.4 Potential Benefits to the Subject

The potential benefits of the Pure-Vu System are utilization of a cleaning technology that may improve the standard colonoscopy visualization, reduce reliance on subject pre-procedure colon preparation for ensuring high quality colonoscopy, increase the subject compliance to colonoscopy procedure and reduce the need for repeated colonoscopies required due to insufficient colon preparation, these consequently may reduce pain, discomfort, risk and cost.

The reduce bowel preparation required when Pure- Vu System is used as compare to standard preparation required prior to colonoscopy procedure without the Pure-Vu System, may increase the subject compliance to the colonoscopy procedure and may reduce the patient’s discomfort caused by the preparation regimens.

Considering the residual risks and the risk against benefit assessment, it can be concluded that the system may offer potential benefit to the patients along with no significant risk increase compared to the standard of care procedure.

8.0 Study Objectives

8.1 Primary objective

To evaluate the performance of Pure-Vu System in cleansing patients' colon who are indicated for a colonoscopy procedure using one of two different bowel preparation regimes.

8.2 Secondary objectives:

- To evaluate the safety related to the Pure-Vu System in both study arms.
- To evaluate the time to reach the Cecum in Pure-Vu procedures in both study arms.
- To evaluate the total procedure time with Pure-Vu in both study arms.
- To evaluate the cecal intubation rate with Pure-Vu in both study arms.
- To evaluative patients' satisfaction with Pure-Vu procedure in both study arms.
- To evaluative Pure-Vu user satisfaction with Pure-Vu procedure in both study arms.

9.0 Study Design

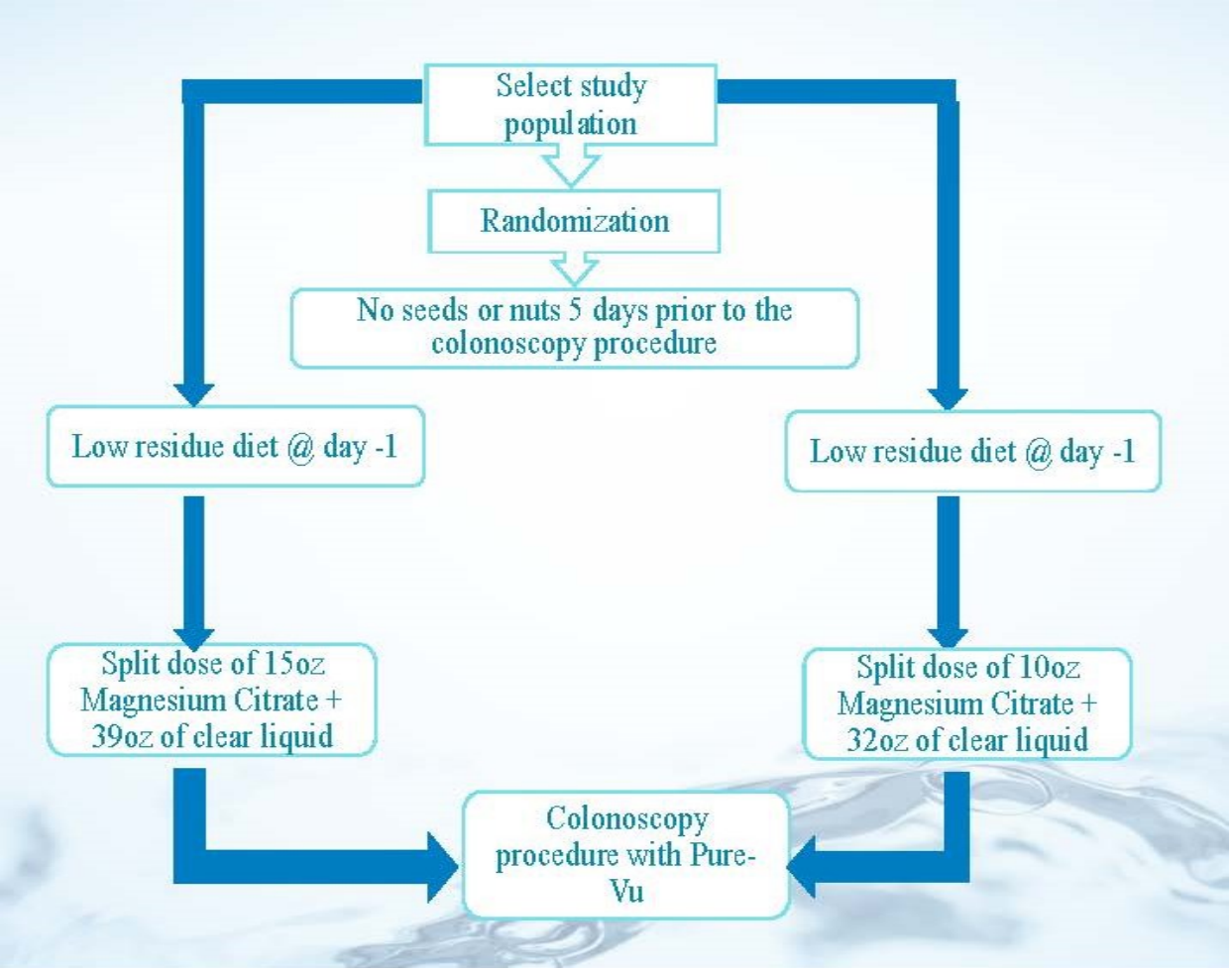
This multicenter, prospective, randomized study will include up to 100 patients (30 patients per site and 15 patients per study arm), aimed at evaluating the performance of Pure-Vu System in cleansing patients' colon who are indicated for colonoscopy procedure using one of two different preparation regimes as detailed below.

Subjects will be enrolled at up to 10 clinical sites in the United States. Subjects who meet the eligibility criteria will be randomly allocated to a given study arm and will be required to follow a specific bowel preparation instruction along with a specific prep agent (Bowel preparation instructions for morning and afternoon procedures are provided in appendix B1 and B2, respectively), as per study arm allocation, starting 5 days prior to the colonoscopy with Pure-Vu. Patients will be asked to record and provide their diet and bowel movements in the provided diary log at time of their scheduled colonoscopy (Diary log is provided in appendix D).

In addition patient will be ask to complete a satisfaction questionnaire include feedback on the procedure and on specific aspects related to the preparation regime.

Following the procedure a telephone follow-up will be conducted at 48 hours (± 48 hours) post Pure-Vu procedure to assess patient well-being and capture any adverse events.

Study Flow chart



9.1 Primary Endpoint

The primary endpoint is the rate of adequate cleansing level per subject evaluated by the BBPS scoring index pre- and post the cleansing operation.

9.2 Secondary Endpoints

The following secondary outcomes will be determined:

- AEs

- Rate of procedures where the cecum was visualized.
- Time to reach the cecum.
- Total procedure time.
- User satisfaction will be evaluated by a questionnaire filled-in by the physicians and nurses who conduct the procedures and assemble the Pure-Vu System.

10.0 Subject Selection and Enrollment

After being informed of the nature of the study, the subject will sign a written informed consent form (ICF) that has been approved by the appropriate IRB of the respective clinical site. Enrollment of up to 100 subjects is planned.

Subjects' participation in the study will last approximately 8 days, including the procedure day, five days prior for bowel preparation, and the follow up period.

Subjects will be considered for the study if they meet the specific inclusion/exclusion criteria. The criteria for enrollment must be followed explicitly.

Enrollment completion is expected to take place up to 12 months following IRB approval of the study.

10.1 Inclusion Criteria

1. Subjects scheduled for colonoscopy procedure
2. Subjects in the age range of 22-75 years inclusive
3. Subject is willing and able to participate in the study procedures and to understand and sign the informed consent.

10.2 Exclusion Criteria

1. Patients with active Inflammatory Bowel Disease
2. Patients with known diverticulitis disease or with prior incomplete colonoscopy due to diverticular disease

3. Patients with known bowel obstruction
4. Patient with chronic constipation
5. History of prior surgery to colon and/or rectum
6. ASA ≥ III
7. Renal insufficiency (Creatinine ≥ 1.5mg /dL) (based on medical history)
8. Abnormal Liver enzymes (ALT/AST ≥ 2 times upper limits of normal) (based on medical history)
9. Patients taking anticoagulants drugs (excluding aspirin) or dual antiplatelet therapy
10. Patients with known coagulation disorder (INR >1.5).
11. Pregnancy (as stated by patient) or breast feeding
12. Patients with altered mental status/inability to provide informed consent

10.3 Withdrawal Criteria

Subjects may withdraw from the study at their own request or at the request of their legally acceptable representative. The investigator may withdraw a subject from the study at any time for the following reasons:

- Severe side effects clearly related to the study device.
- Presence or appearance of exclusion criteria.
- Appearance of accompanying diseases rendering further participation in the study impossible.
- A significant protocol violation, as determined either by the sponsor or the investigator
- Subject noncompliant with investigational procedures
- Subject noncompliant with visits
- At the specific reasonable request of the sponsor

The sponsor must be informed in each withdrawal case. The reason for withdrawal must be recorded in the CRF and in the patient file.

10.4 Selection of Investigators and Training

Board-certified gastroenterologists in accordance with US and hospital guidelines will be considered for participation as investigators in this study. Physicians in training (residents, fellows) and physician assistants may assist the Study Investigator in any aspect of the procedure as per standard procedures and practices at his/her institution.

Each Investigator participating in the clinical trial and the associated clinical study staff will receive training on the clinical protocol. This includes training on AE reporting, case report form (CRF) completion, and Good Clinical Practice (GCP), as well as the device and system (including procedural use, device characteristics, shelf life and storage requirements, warnings, and precautions).

11.0 Study Procedures

11.1.1 Screening and Informed Consent (Visit 1)

Subjects participating in the study may be recruited from investigator's patients' pool.

A screening/baseline visit will be performed within 30 days prior to the scheduled Pure-Vu procedure to assess preoperative eligibility. In the event that the screening and eligibility assessment takes place more than 30 days prior to the planned procedure date, the investigator should contact the subject prior to the procedure date to assure there is no change in the subject's medical condition.

At the screening visit, subjects will be approached to obtain written informed consent prior to any study specific procedures being performed. The purpose of the study and the benefits and risks of the procedures will be explained to the subject and the consent process must be documented accordingly in the medical record. Subjects who agree to study participation must sign an IRB-approved ICF. Subjects will be informed that their participation in this study is voluntary and they may refuse to participate or discontinue from the study at any time. Subjects will be given the opportunity to ask the investigator questions so that they are adequately informed about the research. A copy of the signed informed consent must be provided to the subject and the informed consent process will be documented in source documents.

If new information becomes available that may affect a subject's decision to continue to take part in the study, this information will be discussed with the subject by the investigator.

The following assessments will be performed within 30 days prior to the scheduled procedure and the results recorded on the appropriate subject CRFs:

- Verification of eligibility criteria and subject risk per guidelines
- Demographics (age, gender, height, weight)
- Surgical and medical history (prior abdominal surgery, GI symptoms)
- General medical history will be assessed based on the subject's clinical condition

Recruitment visit:

Patients who meet the eligibility criteria will be screened for study participation and will be randomly allocated to a given study arm at a baseline visit. Patients who are eligible for the study will be required to follow a specific bowel preparation instruction along with a specific prep agent, (Detailed instructions of the study Bowel preparations are provided in appendix B1 and B2) as per study arm allocation, starting 5 days prior to the colonoscopy with Pure-Vu. Subject diaries are provided to the subject at visit 1 to be and will be filled by the subjects during the preparation phase. This will include diet and bowel movement information (diary log is provided in appendix D). The subject is instructed to bring the diary with him/her to the scheduled colonoscopy.

In addition patient satisfaction questionnaire will be provide include feedback on the procedure and on specific aspects related to the preparation regime.

11.1.2 Randomization

Randomization in blocks will be applied for each site to allocate patients to one of two different bowel preparation regimens (Prep A versus Prep B). The study will utilize randomization in blocks using the standard envelope procedure, which will be applied in order to allocate patients into two arms:

- Group 1 - Will go through the Prep A procedure
- Group 2 - Will go through the Prep B procedure

The site randomization plan will be provided to the study coordinator prior the study start. No blinding is applicable in this study.

11.1.3 Screen Failures

A subject is considered enrolled in the study when the ICF is signed. Only subjects who receive study-assigned procedures will be followed. Subjects who provide study consent, but then are determined to be ineligible prior to randomization will be considered screening failures and will

not require additional study follow-up. The reason for the screening failure will be clearly documented, the Subject "Enrollment and Visit Log" will be completed and the subject eligibility section in visit 1 as well as a "Study Completion" form will be completed in the CRF.

11.1.4 Colon Preparation

Subjects will be instructed to follow a detailed dietary and colon preparation regimen prior to the procedure day. All colon preparation products will be standard colon cleansing products approved by the FDA.

Patients will be randomized to one of two bowel preparation regimens (instruction for bowel preparation for morning and afternoon procedures are provided in appendix B1 and B2).

Subjects will keep a timed diary of key preparation steps and bowel activity, in addition questions about the patients satisfaction from the bowel preparation regime and diet instruction will be captured (Appendix D).

11.1.5 Colonoscopy procedure (Visit 2)

Pre-Examination Procedures

- Verify eligibility checked and informed consent was obtained after explaining all risks, benefits, and alternatives to the candidate.
- Verify that the research assistant has collected completed diaries from the subject.
- Verify all background/clinical information, demographic and medical history was documented

Note: Subjects that did not take the bowel preparation or failed to complete the bowel preparation will not undergo the procedure and will be excluded from the study.

- Verify all connections and assembles are properly attached (see Instructions for Use)
- Verify device works properly (see Instructions for Use)
- Place and prepare the subject for the procedure as per standard colonoscopy.
- Perform a digital rectal exam as per standard colonoscopy, evaluate the adequate level of the preparation and start the colonoscopy procedure with the Pure-Vu System as per standard of care.

Pre-Examination Procedures

The procedure will be performed by the clinical investigator(s), experienced in GI endoscopy according to local standard of care. Anesthesia will be applied as well per the standard of care. In

order to ensure correct operation of the Pure-Vu System a Motus GI representative may attend the procedure. Using the Pure-Vu, requires specific training with the device that will be provided by the sponsor prior to the study. Pure-Vu System operation is described in the Instruction for Use.

Colonoscopy Procedures

The colon preparation level for each colorectal segment (ascending, transverse and descending) before the cleansing operation during the insertion phase and post the cleansing operation during withdrawal will be evaluated using the BBPS scoring index (Appendix C).

Once the procedure is completed, relevant data will be recorded on the CRF in addition, findings, diagnosis as well as Physician questionnaire will be recorded/completed.

The colonoscopy examination with the Pure-Vu will be recorded on VCR or DVD. Only the subject study ID and initials should appear in the recorded video.

The cecum will be documented in a picture.

All optical colonoscopy still pictures will be saved in a digital format. Quality copies of the pictures taken during optical colonoscopy will be provided to the sponsor with the optical colonoscopy report.

These videos and pictures will be archived and may be used in future analyses to, for example, provide further information about observed lesions or to assess study quality.

Specific situations occurring during colonoscopy

- If the attempt to reach the cecum is failed, the investigator shall perform the procedure with a pediatric or any other colonoscope he/she may choose without the Pure-Vu. The subject will complete the study as planned.
- If a medical condition requiring treatment is detected during colonoscopy, the subject will be treated as per the standard care.

Post-Examination Follow-up

Subjects will be transferred to recovery room for observation per standard colonoscopy protocol. Subjects will be contacted by phone 2 working days after the procedure to verify that there has been no change in their well-being. Any AE will be documented in the CRF.

In addition questions about the patients' satisfaction with the Pure-Vu procedure will be completed.

Before a subject is considered "lost to follow-up", there must be at least two documented attempts to contact the subject.

11.2 Required Concomitant Medications or Therapies

All the medications used in this study are FDA approved, Commercial off-the-shelf products.

12.0 Statistical Analysis

12.1 Sample Size Determination

This is a pilot study that will include up to 100 patients; no statistical considerations were made to determine the sample size.

12.2 Description of statistical methods

Basic demographic and other baseline characteristics will be collected and analyzed for all patients. Summary statistics (arithmetic mean, standard deviation, median, minimum and maximum for quantitative variables) will be presented for the total study population. Frequency tables for qualitative data will be provided.

Any deviation from specified statistical plan will be in addition to "per protocol" analysis and will be reported as such. Intent-To-Treat and Post-hoc analysis will be conducted according to the existing data gathered, if necessary.

In addition, in cases of an incomplete procedure (i.e., the entire colon is not visualized); the overall BBPS per patient will be evaluated based on the colon segments that were visualized.

12.3 Primary Endpoint Hypothesis Analysis

The primary endpoint is the rate of adequate bowel cleansing level after the use of the Pure- Vu.

The rate of adequate cleansing level in each colon segment before and after use of Pure-Vu will be evaluated using the Boston Bowel Preparation Scale (BBPS).

A score of 0 - 3 will be given to each of the 3 segments of the colon (Descending, Transverse and Ascending).

BBPS scores will be rated by the endoscopist, on the basis of three segment scores summed for maximum score of 9, where:

- 0 = unprepared
- 9 = completely clean (in completed to Cecum procedures)

An adequate cleansing procedure is defined as when all 3 colon segments are graded as 2 or 3.

Chi-square or Fisher's exact test, as appropriate, will be performed in order to compare proportions of good or excellent cleansing level between the two preparation procedures.

12.4 Effectiveness Analyses

Safety Analysis

The secondary endpoint is to evaluate the Device related adverse event and the overall adverse events rate. The safety analysis set will consist of all patients who were enrolled into the study.

Individual listings of adverse events including type of device, adverse events (reported term), seriousness, duration, relationship to the study device, severity and the adverse events outcome will be provided for the total population and per study arm. AEs will be summarized using frequency counts and percentages per study arm.

Cecum intubation rate

Completion of colonoscopy with the Pure-Vu System is defined from insertion of colonoscope to visualization of the cecum. Cecal intubation will be evaluated by the percent of colonoscopy procedures that reached the cecum.

Proportion (Chi-square or Fisher's exact) tests will be performed in order to compare between the two preparation procedures for the following endpoint based on binary measure.

In addition, frequency counts, percentages, and 95% confidence intervals will be provided.

Time analysis

T-tests for continuous variables will be performed in order to evaluate the difference between the two preparation procedures for the following endpoints:

- Time to Cecum- defined as the duration from colonoscope insertion to visualization of the cecum.

- Total Procedure time- defined as the time from colonoscope insertion to removal. (guide: >6mintues withdrawal time)

These endpoints will be summarized using descriptive statistics, including number of subjects, mean, median, standard deviation, minimum, and maximum.

Patient Satisfaction

Patient satisfaction will be evaluated by a questionnaire (Appendix E). The patient will be asked to fill-in a questionnaire and include their feedback on the procedure including specific aspects related to the preparation regime.

Patient satisfaction will be summarized in a table via descriptive statistics by data type. Chi-square or Fisher's exact test, as appropriate, will be performed in order to compare the patient satisfaction between the two study arms.

User Satisfaction

User satisfaction will be evaluated by a questionnaire (Appendix F). The physicians who conduct the procedures will be asked to answer questions related to usability and efficacy of Pure-Vu.

User satisfaction will be summarized in a table via descriptive statistics by data type. Chi-square or Fisher's exact test, as appropriate, will be performed in order to compare the user satisfaction between the two study arms.

12.5 Analysis Populations

Cases withdrawn prior to the Pure-Vu procedure and those with technical failure will be excluded from the efficacy analysis. All patients who undergo bowel preparation will be included in the safety analysis.

Individual listings of withdrawal / failure including descriptive information will be provided.

In addition, in cases of incomplete procedure (i.e., the entire colon is not visualized); the overall BBPS per patient will be evaluated based on the colon segments that were visualized.

12.6 Interim Analyses

No interim analysis is planned in this study.

12.7 Potential Limitations

Several potential limitations of the study are acknowledged:

- The sample size is not statistically powered for this feasibility study. While this may limit the study interpretation, the study objective is to evaluate whether Prep B will tend to have better outcomes compared to Prep A in order to inform future clinical research studies.
- Because this study uses a standard-risk cohort, the result may not be generalizable to high-risk cohorts.

13.0 Adverse Events (AEs) and Complications

AE and AE subcategories are defined per ISO14155:2011, as described below.

13.1 Adverse Event (AE)

An AE is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, whether or not related to the investigational medical device.

This definition includes events related to the investigational medical device or the comparator and the procedures involved.

AEs will be collected starting from the time subject is enrolled until the follow-up period is completed.

13.2 Serious Adverse Event (SAE)

A Serious AE (SAE) is an AE that has

a) Led to death,

b) Led to serious deterioration in the health of the subject, that either resulted in

1) A life-threatening illness or injury, or

2) A permanent impairment of a body structure or a body function, or

3) In-patient or prolonged hospitalization, or

4) Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

c) Led to fetal distress, fetal death or a congenital abnormality or birth defect

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without serious deterioration in health, is not considered an SAE.

Some important medical events, although they may not result in death, be life-threatening, or require hospitalization may still be considered SAEs when, based upon appropriate medical judgment, they are felt to jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

Life threatening means that the subject was, in the view of the investigator, at immediate risk of death from the reaction as it occurred. This does not include an AE that, if more severe, might have caused death.

Disability means a substantial disruption of a person's ability to conduct normal life's functions.

13.3 Adverse Device Effect (ADE)

An Adverse Device Effect (ADE) is an AE related to the use of an investigational medical device.

This definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

13.4 Serious Adverse Device Effect (SADE)

A Serious Adverse Device Effect is an adverse device effect that has resulted in any of the consequences characteristic of an SAE.

13.5 Unanticipated Serious Adverse Device Effect (USADE)

An Unanticipated Serious Adverse Device Effect is a serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report.

13.6 Adverse Event Severity Classification

Severity will be defined according to the following criteria:

Mild	Awareness of event, but easily tolerated
Moderate	Discomfort enough to cause some interference with activities of daily living (ADL)
Severe	Incapacitating, with an inability to perform ADL

An AE can be classified as severe and not deemed a SAE. Similarly, a SAE is not automatically severe in nature.

13.7 Adverse Event Relationship Classification

Relationship to study product administration will be determined as follows:

- *No Relationship*: No relationship between the AE and the administration of study treatment and a known relationship to other etiologies such as concomitant medications, procedure, or subject's clinical state.
- *Possible Relationship:* An AE that follows a reasonable temporal sequence from administration of the study treatment and follows a known response pattern to the study treatment but could have been produced by the participant's clinical state or by other therapies.
- *Probable Relationship:* An AE that follows a reasonable temporal sequence from administration of the study treatment; follows a known response pattern to the study treatment; and cannot be reasonably explained by the known characteristics of the participant's clinical state or by other therapies.
- *Definite Relationship:* An AE that follows a plausible temporal sequence from administration of the study treatment and follows a known response pattern to the study treatment. The reaction cannot be reasonably explained by the known characteristics of the subject's clinical state or other modes of therapy administered to the subject.

- *Unknown/Impossible to Determine:* Given the information available, sequence and timing of events, it is unknown or impossible to determine the relationship of the AE with the study treatment.

13.8 Adverse Event Outcome Classification

Outcome of the event will be defined according to the following:

- *Resolved:* The event has fully resolved at the end of the study.
- *Resolved with sequelae*: The event has resolved, but retained pathological conditions resulting from the prior disease or injury.
- *Continuing:* The event is ongoing at the end of the study.
- *Death:* This event is determined to be the cause of death.

13.9 Device Deficiencies

A device deficiency is an inadequacy of a medical device related to its identity, quality, durability, reliability, safety, or performance, such as malfunction, misuse or use error and inadequate labeling.

All device deficiencies will be documented and the device should be returned to Motus GI for analysis, if possible. Instructions for returning the investigational device will be provided. Device deficiencies should also be documented in the subject's medical record.

Device deficiencies are NOT to be reported as AEs. However, if there is an AE that results from a device deficiency, that specific event would be recorded on the appropriate CRF.

13.10 Adverse Event Recording and Reporting

Assessment of the occurrence of an AE will be based on changes in the subject's signs and symptoms. AEs will be monitored until a subject completes the study unless the Investigator determines the event is related to the investigational device, in which case they will be monitored until resolution if possible. Medical care will be provided, as defined in the informed consent, for any AE related to study participation. AEs will be collected on an AE CRF and applicable source documentation.

The following should not be considered an AE:

- A condition requiring a preplanned procedure unless the condition worsened since screening
- A preexisting condition found as a result of screening, unless the condition has worsened since enrollment.

All AEs observed during the course of this study, regardless of severity or relationship to the investigational device will be recorded on the appropriate CRF.

13.11 Reporting Responsibilities

An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated SAEs, ADEs, SADEs, USADEs, and device deficiencies that could have led to a serious adverse device effect occurring during an investigation within 24 hours of learning of the event, but in no event later than 10 working days after the investigator first learns of the effect.

A sponsor who conducts an evaluation of an unanticipated adverse device effect under 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests (21 CFR Part 812.150).

14.0 Ethics and Compliance

14.1 Statement of Compliance

This clinical investigation will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, ISO 14155:2011 (Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice), ICH-GCP, and any regional or national regulations, as appropriate.

This may include an inspection by Motus GI representatives and/or Regulatory Authority representatives at any time. The investigator must agree to the inspection of study-related records by the Regulatory Authority/ Motus GI representatives, and must allow direct access to source documents to the Regulatory Authority/ Motus GI representatives. Regulatory Authority approvals/authorizations/notifications, where required, will also be in place and fully documented prior to study start.

14.2 Protocol Compliance

No changes to the protocol will be permitted without the written approval from Motus GI and the IRB. The investigator must notify Motus GI and the reviewing IRB of any deviation from the Investigational Plan when specific to the protection of the life or physical well-being of a subject in an emergency. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency has occurred. Except in such an emergency, prior written approval by Motus GI is required for changes in or deviations from the Plan. If these changes or deviations affect the scientific soundness of the Plan or the rights, safety, or welfare of human subjects the IRB will also be notified. All other deviations will be reported per the site's IRB deviation policy. Should any deviations from the Investigational Plan occur, these will be reviewed by Motus GI for their clinical significance. If the event is performed without written approval from all parties, the investigator may be terminated from the study.

14.3 Institutional Review Board (IRB)

Documented approval from the appropriate Institutional Review Board (IRB) will be obtained for all participating centers prior to study start, according to ICH GCP, local laws, regulations, and organization. When necessary, an extension, amendment, or renewal of the IRB approval must be obtained. The IRB must supply to the sponsor a list of the IRB membership and a statement to confirm that the IRB is organized and operates according to GCP and applicable laws and regulations.

14.4 Subject Informed Consent

A core information and consent form will be provided. Prior to the beginning of the trial, the investigator must have the IRB written approval/favorable opinion of the written ICF and any other written information to be provided to subjects. The written approval of the IRB together with the approved subject information/ICFs must be filed in the study files.

The process of obtaining informed consent must be in accordance with applicable regulatory requirement(s), and must adhere to GCP and to the ethical principles originating in the Declaration of Helsinki. Written informed consent must be obtained before any study specific procedure takes place. Participation in the trial and date of informed consent given by the subject should be documented appropriately in the subject files.

14.5 Insurance

All subjects participating in the trial will have insurance coverage by the Sponsor, which is in line with applicable local laws.

14.6 Confidentiality

All records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

Subject names will be kept confidential. Only the subject number and initials will be recorded in the CRF, and if the subject name appears on any other document, it must be obliterated. In cases were the local low does not allow using the subject initials serial number will be appointed (e.g. AAA, BBB). Study findings stored on a computer will be stored in accordance with local data protection laws. The subjects will be informed in writing that representatives of the sponsor, IRB or Regulatory Authorities may inspect their medical records to verify the information collected, and that all personal information made available for inspection will be handled in strictest confidence and in accordance with local data protection laws. Subjects will also be informed that information regarding the study that does not include subject identifiers will be posted on clinicaltrials.gov.

If the results of the trial are published, the subject's identity will remain confidential.

The investigator will maintain a list to enable subjects' records to be identified.

14.7 Use of Data and Publications

Information regarding the study and study data will be made available via publication on clintrials.gov.

All data and results and all intellectual property rights in the data and results derived from the study will be the property of Motus GI, who may utilize the data in various ways, such as for submission to government regulatory authorities or disclosure to other investigators, educational, further product development and marketing uses.

The investigator, while free to utilize data derived from the study for scientific purposes, must discuss any publication with the sponsor prior to release and obtain written consent of the sponsor on the intended publication. The sponsor recognizes the right of the investigator to publish the results upon completion of the study. However, the investigator must send a draft

manuscript of the publication or abstract to the sponsor 45 days in advance of submission in order to obtain approval prior to submission of the final version for publication. This will be reviewed promptly and approval will not be withheld unreasonably. In case of a difference of opinion between the sponsor and the investigator(s), the contents of the publication will be discussed in order to find a solution which satisfies both parties.

Disclosure of involvement in a publication (e.g., sponsor of the study; collection, analysis, and interpretation of data; professional writing assistance) must be as specified by journal-specific policies, submission requirements, and prevailing editorial standards, in addition to those specified by International Committee of Medical Journal Editors. Authors must ensure that an acknowledgement/disclosure statement is included in the body of the manuscript for Motus GI to review for accuracy. All authors must also disclose financial or personal affiliations that could be considered conflicts of interest as per journal requirements.

15.0 Monitoring Procedures

Site visits will be conducted by an authorized Motus GI representative to inspect study data, subjects' medical records, and CRFs in accordance with current ICH GCPs and the respective local and national government regulations and guidelines (if applicable).The Study Investigator and the investigating site will permit authorized clinical research personnel and clinical monitors from Motus GI and/or designee(s) employed by Motus GI to review completed CRFs, IRB decisions, and Investigator, clinical site records, and facilities relevant to this study at regular intervals throughout the study per the monitoring plan. Additionally, subject charts and clinical records will be requested and reviewed so that protocol adherence and source documentation can be verified. The accuracy and quality of the data obtained from the investigator and maintained by Motus GI will be confirmed through a structured program of clinical field auditing and internal review detailed in the monitoring plan. In instances where data protection regulations prohibit the direct examination of hospital records by the study Sponsor or designee(s), the Investigator will cooperate in a system of source data verification with the Sponsor. Monitoring may be performed with in person visits or remotely, when applicable.

To ensure the rights, safety, and welfare of study subjects are being maintained, the monitor will review training records to ensure all study staff are trained on the study protocol and use of the study devices. If the monitor discovers that an investigator is not complying with the signed Investigator Agreement, the investigational plan, applicable laws, or any conditions of approval

imposed by the reviewing IRB, the monitor will report to the Sponsor and take such steps necessary to promptly secure compliance. If compliance cannot be secured, device shipments to the investigator may be discontinued and the investigator's participation in the investigation terminated. The monitor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

15.1 Data Collection and Processing

This study will utilize a (Case Report Form) CRFs. All data requested on the CRFs are considered required. Data points not collected and/or recorded will be considered deviations unless otherwise specified.

The Principal Investigator must ensure the accuracy and completeness of the recorded data and then provide his/her signature on the appropriate CRFs and will be documented in compliance with local regulations. Changes to data previously submitted to the sponsor will require a new signature by the Investigator to acknowledge/approve the changes.

Visual and/or computer data review will be performed to identify possible data discrepancies. Manual and/or automatic queries will be created and will be issued to the site for appropriate response. The site staff will be responsible for resolving all queries in the database.

16.0 Study Supplies and Device Accountability

16.1 Packaging

The Pure Vu disposables are composed of biocompatible plastic parts and are supplied clean in a sealed package. The shelf life of the device was tested within the device verification and validation process to support shelf life period of 9 months.

16.2 Labeling

All equipment associated with the clinical trial will be identified with visible markings stating "Exclusively for clinical investigation only".

All packages are labeled in conformance to Motus GI Packaging Best Practice, which are applicable to Single Use, Limited Shelf Life, Lot produced items. Examples of the main system

and packaging label as well as operation instructions, precautions and warnings are defined in the "Instructions For Use".

16.3 Inventory Control

The sponsor will initiate shipment of the product from the sponsor to the site upon receiving all required documents (e.g., approval/favorable opinion from IRB). The sponsor will maintain tracking for all shipment documentation. Prior to any shipment, the site will be informed by the sponsor of the upcoming shipment, expected arrival date, and content of the shipment. The site should confirm receipt of the shipment. The site will file the Sponsor's Shipping Receipt in the Sponsor's Study File.

An Investigator's Device Accountability form will be conducted under the Regulatory Binder at each site and will be monitored by the site's clinical research associate (CRA).

In case of technical failure, the site will approach the technical support team which will help solve the problem and will notify the site's CRA.

For each dispensed Pure-Vu Oversleeve, the following information should be recorded:

- The subject study number
- Date dispensed
- Disposables' ID number

At the termination of the study, all unused study material must be returned with the corresponding documentation as directed by Motus GI.

16.4 Retention of Records

All source documents and CRFs will be kept for a period of no less than five years after the later of the following dates: the date of which the study is terminated or completed or; the date that the records are no longer required supporting marketing applications.

16.5 Study Completion/Termination of Study

Motus GI reserves the right to discontinue the study at any stage, with suitable written notice to all investigators and reviewing IRBs, following unforeseen events or other factors that do not permit continuation of the study. Similarly, investigators may withdraw from the study at any time, subject to providing written notification to Motus GI 30 days prior to the date they intend

to withdraw. However, Motus GI and investigators will be bound by their obligation to complete the follow-up of subjects already participating in the study. The subjects must be followed according to the clinical protocol, and information obtained during subject follow-up shall be reported to Motus on the appropriate eCRF.

The appropriate ethics committees will be notified of discontinuation of the trial for any reason not later than 5 working days after the sponsor makes this determination and not later than 15 days after the sponsor receives a notice from the ethics committee and/or regulatory authority.

17.0 General Information

17.1 Study Contact Information

Questions should be directed to Clinical Affairs.

Clinical Affairs
Ravit Peled Director of Clinical Affairs Motus GI Technologies LTD. Keren Ha'yesod 22 3902638 Tirat Carmel, Israel Phone: +972 (73) 3243823 ext:203 Mobile: +972 (52) 614-5354 Email: Ravit@motusgi.com

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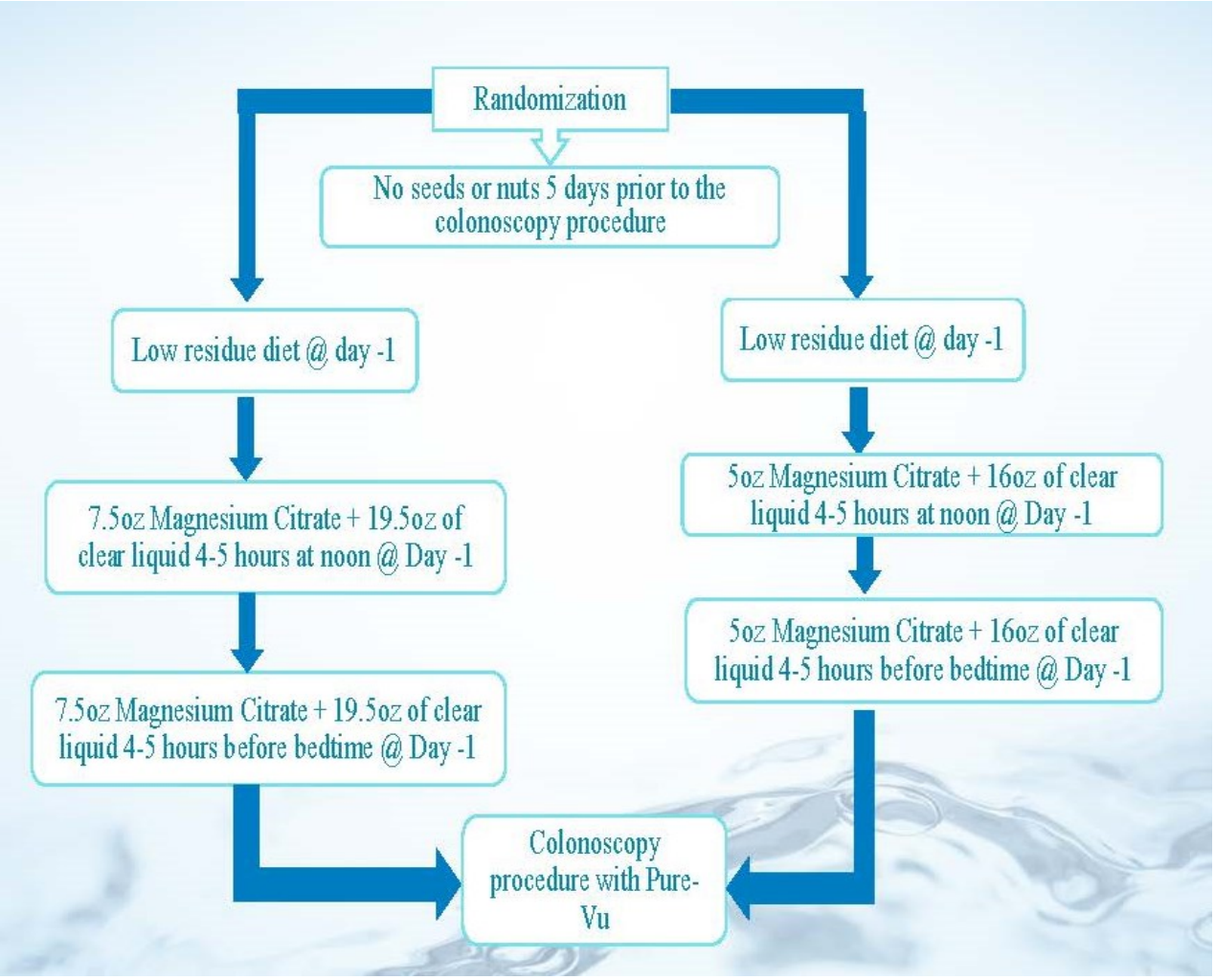
19.0 Appendixes A: Study Design and Schedule of Assessment

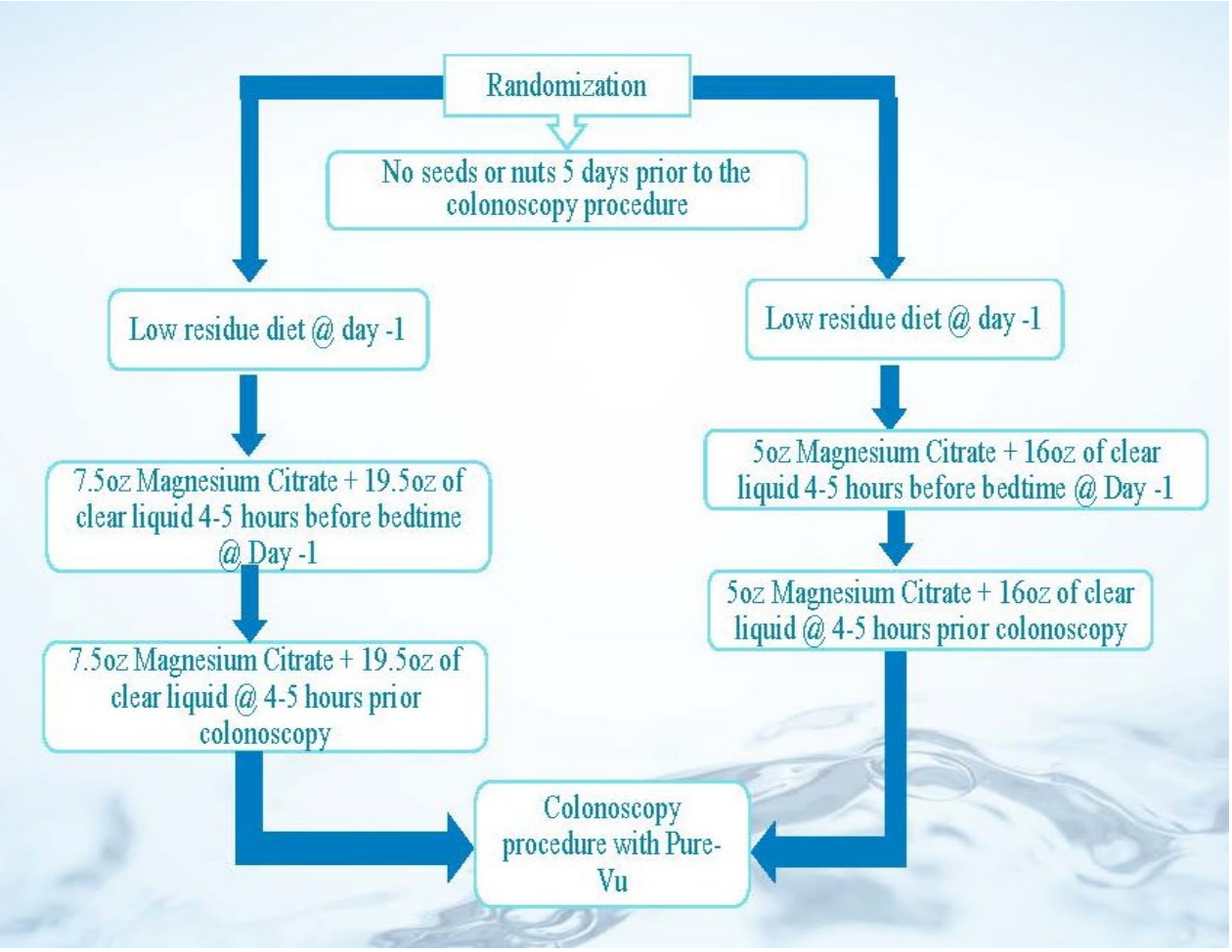
Visit	Visit 1	Colon Preparation	Visit 2	Contact
Days	**>-5 days**	**-1 to 0 days**	**0**	**48 hours**
Informed Consent*	X			
Eligibility assessment (medical records, BMI, etc.)	X			
Randomization	X			
Colon Preparation Instructions	X			
Medical History, Concomitant Medications, Demographic details	X			
Diaries	X (providing)	X (by the patients)		
Patients' satisfaction questionnaire	X (providing)	X	X	
Bowel Preparation		X (by the patients)		
Colonoscopy Procedure			X	
Follow Up			X	X
Adverse Events Reporting		X		

20.0 Appendixes B: Bowel Preparation flow chart

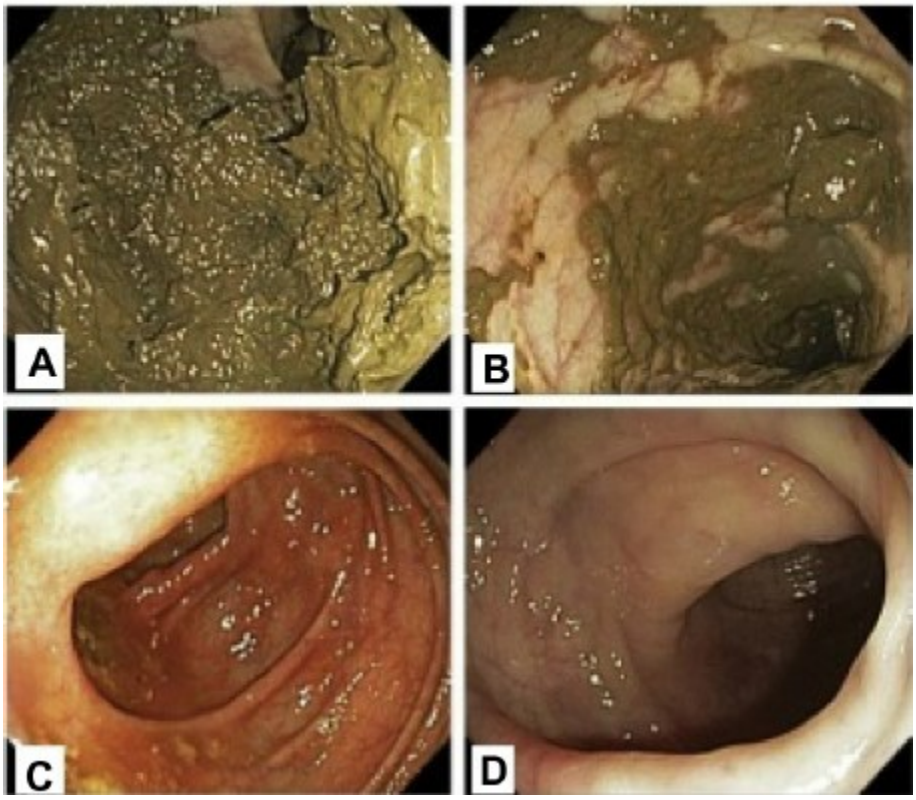
20.1 Appendixes B1: Bowel Preparation for morning procedures



20.2 Appendixes B2: Bowel Preparation for afternoon procedures



21.0 Appendixes C: Boston Bowel Preparation Scale



- **A: Score 0-** Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared.
- **B: Score 1** - A portion of the mucosa of the colon segment is seen, but other areas of the colon segment are not seen well due to staining, residual stool, and/or opaque liquid.
- **C: Score 2-** A minor amount of residual staining, small fragments of stool, and/or opaque liquid are visible, but the mucosa of the colon segment are seen well.
- **D: Score 3-** The entire mucosa of the colon segment is seen well with no residual staining, small fragments of stool, or opaque liquid.

22.0 Appendix D – Patient Diary

22.1 Diet Instructions for morning procedures

No Seeds or Nuts 5 day before your procedure

Drink at least two liters of CLEAR LIQUIDS per day beginning at 2 days prior to your procedure

On the day before your Procedure You Can Eat the Following:

Breakfast	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread + cheese spread/ cottage cheese/ butter/ margarine/ 1 Tables poon of mayonnaise/ honey ☐ 1 plain yogurt/sour cream ☐ Scrambled eggs (1-2 eggs) ☐ Tea sweetened with white sugar or coffee added with a small amount of milk/cream
Lunch	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread with cheese spread, butter, margarine, honey. ☐ 4-6 oz of chicken soup containing skinless chicken, peeled potato, no vegetables. ☐ Pasta or noodles with butter (no red sauce) or white rice
Dinner	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread + cheese spread/ cottage cheese/ butter/ margarine/ 1 Tables poon of mayonnaise/ honey ☐ 1 plain yogurt/sour cream ☐ Pasta or noodles with butter (no red sauce) or white rice ☐ Clear chicken soup ☐ Tea sweetened with white sugar or coffee added with a small amount of milk/cream

On the procedure day:

Clear-liquid diet up to 3 hours prior to the procedure

Fasting (no food / liquids) start 3 hours prior to procedure time

22.2 Diet Instructions for afternoon procedures

No Seeds or Nuts 5 day before your procedure

Drink at least two liters of CLEAR LIQUIDS per day beginning at 2 days prior to your procedure

On the day before your Procedure You Can Eat the Following:

Breakfast	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread + cheese spread/ cottage cheese/ butter/ margarine/ 1 Tables poon of mayonnaise/ honey ☐ 1 plain yogurt/sour cream ☐ Scrambled eggs (1-2 eggs) ☐ Tea sweetened with white sugar or coffee added with a small amount of milk
Lunch	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread with cheese spread, butter, margarine, honey. ☐ 4-6 oz of chicken soup containing skinless chicken and peeled potato. ☐ Pasta or noodles with butter (no red sauce) or white rice
Dinner	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread + cheese spread/ cottage cheese/ butter/ margarine/ 1 Tables poon of mayonnaise/ honey ☐ 1 plain yogurt/sour cream ☐ Pasta or noodles with butter (no red sauce) or white rice ☐ Clear chicken soup ☐ Tea sweetened with white sugar or coffee added with a small amount of milk

On the day of your Procedure You Can Eat a light breakfast as the Following:

Breakfast	☐ 20 oz of clear liquid ☐ 1-2 slices of white bread + cheese spread/ cottage cheese/ butter/ margarine/ 1 Tables poon of mayonnaise/ honey ☐ 1 plain yogurt/sour cream ☐ Tea sweetened with white sugar or coffee without milk/cream

Clear-liquid diet up to 3 hours prior to the procedure

Fasting (no food / liquids) start 3 hours prior to procedure time

22.3 Meal and Liquids Log

Please indicate the type and value of the food and liquids you consumed during the preparation days:

		Day -1 (Day prior to procedure)	**Day of Procedure** Nothing Per Oral 3 Hours Prior to Colonoscopy
Breakfast	Food		
	Volume and Type of Clear Liquids		
Lunch	Food		After the procedure please return to your normal daily diet
	Volume and Type of Clear Liquids		
Dinner	Food		
	Volume and Type of Clear Liquids		

22.5 Bowel Movements Log

Day -1 (Day prior to procedure)	Day of Procedure
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid
Time of BM: Please Circle: Formed or Liquid	Time of BM: Please Circle: Formed or Liquid

23.0 Appendix E – Case Report Form (filled-in by the patient)

Pure-Vu™
Patient Satisfaction Questionnaire

Procedure Date / Patient ID Number:_____/_____

Physician Name: _____

The patient will answer the following questions prior the colonoscopy procedure

Question #1	**Yes**	**No**
Was this your first colonoscopy?		

Question #2	**Very Easy**	**Easy**	**Tolerable**	**Difficult**	**Very Difficult**
How tolerable did you find the low fiber diet in this bowel preparation process?					
How tolerable did you find the bowel cleansing purgative in this bowel preparation process?					
How disruptive was the bowel preparation process to your normal activities?					

Question #3
If you could change two things in the bowel preparation process, what would they be?
1
2

The patient will answer the following questions after the colonoscopy procedure during the follow up phone call (will be filled by the site study coordinator)

Question #4	**Yes**	**No**
Based upon your experience with Pure-Vu, would you recommend Pure-Vu to your friends and family members who need a colonoscopy?		

Please explain why:

_____

_____

Question #5	**Yes**	**No**
Would you request Pure-Vu for your next colonoscopy?		

Question #6	**Yes**	**No**
Would you request Pure Vu again for your next colonoscopy if it cost $300?		

If this was not your first colonoscopy, please answer questions 7 – 11.
Please answer question 7-10 *prior the colonoscopy procedure*. Please add any additional comments at the end of the questionnaire

Question #7	**Yes**	**No**
Was this preparation different from your previous preparation?		

If the preparation was different, please explain how and / or why:

_____

_____

Question #8	This Pure-Vu prep was more tolerable than before	This Pure-Vu prep was about the same as before	This Pure-Vu prep was less tolerable than before
How would you compare the tolerability of the preparation with Pure-Vu to your previous colonoscopy?			

If the tolerability of this preparation was different, please explain how and / or why:

_____

_____

Question #9	Pure-Vu diet was better than before	Pure-Vu diet was about the same as before	Pure-Vu diet was worse than before
How would you compare the dietary restrictions with Pure-Vu to your previous colonoscopy?			

If your dietary experience was different, please explain how and / or why:

_____

_____

Question #10	Pure-Vu experience was less disruptive than before	Pure-Vu experience was about the same as before	Pure-Vu experience was more disruptive than before
How would you compare the disruption to your daily activities with Pure-Vu to your previous colonoscopy experience?			

If the disruption to your daily activities was different, please explain how and / or why:

_____

_____

The patient will answer the following question after the colonoscopy procedure during the follow up phone call (will be filled by the site study coordinator)

Question #11	Pure-Vu experience was better than before	Pure-Vu experience was about the same as before	Pure-Vu experience was worse than before
How would you compare your overall Pure-Vu experience to your previous colonoscopy experience?			

If your experience was different, please explain how and / or why:

_____

_____

24.0 Appendix F – Case Report Form (filled-in by the physician)

Site No. **Subject No.** **Subject Initials**

Study arm: ☐ **Magnesium Citrate 10 oz** ☐ **Magnesium Citrate 15 oz**

Physician Name: _____

Date subject signed the informed consent form: ____ / ___ / ____
DD MM YY

Date investigator/designee signed the informed consent form: ____ / ___ / ____
DD MM YY

Did the subject satisfy all enrollment criteria? □Yes □ No (if No, please specify which criterion was not met)

_____

Procedure date: ____ / ___ / ____
DD MM YY

Patient Gender / Age: _____ / ____

Patient Height (cm) / Weight (kg): _____ / _____

Please check all indications that apply for the patients' colonoscopy	**Please Check**
Screening	
Bleeding	
Polyp surveillance	

IBD surveillance	
Family history (1st degree relative)	
Anemia	
Other: Please specify	

Prescribed Prep	**Completed Yes / No**
Magnesium Citrate 10oz:	
Magnesium Citrate 15oz:	

	HH : MM
Colonoscopy start time	
Time cecum reached	
Time colonoscopy ended	

Please rate the bowel prep	**BBPS Rating Prior to Use of Pure-Vu (0 - 3)**	**BBPS Rating After Use of Pure-Vu (0 - 3)**
Descending colon		
Transverse colon		
Ascending colon		

Comments: _____

_____

	Sigmoid / Descending	**Transverse**	**Ascending**
If the cecum was not reached during the colonoscopy procedure, please indicate the furthest anatomical landmark reached			

If cecum not reached, please indicate the reason	**Please Check**
Poor bowel cleanliness	
Patient intolerance / discomfort	
Clinical and anatomical (such as stricture, redundant colon, etc.)	
Other: Please specify _____ _____	

Usability	**Excellent**	**Good**	**Acceptable**	**Difficult**	**Unacceptable**
Ease of colonoscope advancement with Pure-Vu					
Ease of navigating colonoscope with Pure-Vu					
Torque ability of colonoscope with Pure-Vu					
Ease of sigmoid passing					
Ease of retroflex					

Were there any polyps detected during the procedure? □Yes □ No

Polyp Size (mm)	**Polyp location**	**Histology results**	**Type of intervention**	**Time of Intervention (mins)**

Comments:

_____

_____

Follow Up information	**DD / MM / YY**
48 hours follow up call date	___ / ___ / ____
Follow up outcome:	

Report Serious Adverse Event (SAE) within 48 hours of learning the event

Adverse Event (AE) Form	**Please Check**
Have any AEs occurred during the study?	Yes / No
If yes,	
Start Date	__ / __ / __ DD MM YY
End Date	__ / __ / __ DD MM YY
Description:	• Tissue trauma • Excessive bleeding • Laceration • Other: _____ • Death
Severity	• Mild • Moderate • Severe
Anticipated	Yes / No
Relation to the study	• Unrelated • Unlikely • Possibly • Related
Was the AE serious AE?	Yes / No
If yes, specify the reason	• Death • Life threatening • Hospitalization • Persistence / significant disability / incapacity • Congenital anomaly / birth defect • Important medical event (subject's health is at risk and intervention is required to prevent one of the above events) , specify

	Date of Event report to the IRB: __ / __ / __ DD MM YY
Treatment?	Yes / No
If yes, specify type and reason	Pharmacological treatment _____ Other medical intervention _____
Outcomes	• Resolve • Improved • Unchanged • Worsen • Insufficient follow up • Comments: _____
Investigator signature Date	_____ __ / __ / __ DD MM YY