SCOUT DS® Noninvasive Diabetes Screening Device

Canadian Operation Manual

Instructions for Use

VeraLight

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1. NOTATIONAL DESCRIPTIONS

a. Notation

Throughout this manual, there are blocks of text in bold type. These blocks are notes and are used as follows:

NOTE: A NOTE provides important general information that will help you make better use of the SCOUT DS.

b. Symbols

SYMBOL	Description
	General Warning Symbol (to be followed by Warning Information)
	Consult Instructions for Use
	Manufacturer (Manufactured By)
	Date of Manufacture
REF	Reference or Product Number
SN	Serial Number of the Device
	Contains Sufficient for <n> Tests (Number of Tests Available)

2. INTRODUCTION

a. Indications for Use

The SCOUT DS is indicated for noninvasive screening of individuals 18 years or older who are at risk for prediabetes and/or type 2 diabetes to determine whether diagnostic testing is necessary. Prediabetes is defined as impaired glucose tolerance.

b. Features

The key features of the SCOUT DS include:

- Noninvasive
- No biohazards
- No fasting required; test any time of day
- Built-in quality checks
- Step-by-step guidance through the measurement process
- 3 to 5 minute test time
- Measurement result reported immediately

c. Diabetes Screening Background

Type 2 diabetes is a very serious disease that is increasing at alarming rates worldwide. People with type 2 diabetes are much more likely to have a heart attack or stroke. In addition, type 2 diabetes often leads to debilitating complications of the eye (retinopathy, macular edema, blindness), nerves (autonomic and peripheral neuropathy, lower limb amputations), and kidney (nephropathy, renal failure). Overall, many people with type 2 diabetes have a shorter life expectancy and compromised quality of life.

Screening for type 2 diabetes is important because the disease is progressive with a long latent phase that is absent of symptoms. The Canadian Diabetes Association (CDA), American Diabetes Association (ADA), and World Health Organization (WHO) have defined a prediabetes phase where a person has elevated glycemia but has not yet reached a level considered to be diabetes.[1,2,3] Multiple randomized and controlled clinical trials have demonstrated that detection and treatment of people with prediabetes can prevent or delay the onset of type 2 diabetes.[4,5,6,7] In addition, the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that for people with

type 2 diabetes, intensive therapy intended to maintain near normal glycemia was effective at reducing the incidence of both micro and macrovascular complications.[8]

The CDA,[1] ADA,[2] and WHO[3] recommend some or all of the following tests for diabetes screening:

- Fasting plasma glucose (FPG): measured in the morning after a minimum 8 hour fast
- Oral glucose tolerance test (OGTT): measured in the morning after a minimum 8 hour fast, consumption of a 75 gm glucose load and based on the two-hour post challenge plasma glucose
- A1C: measured any time of day without regard to fasting status

The OGTT is considered the gold standard for diabetes screening because it is more sensitive and there is a wealth of epidemiological data using this test. However, the OGTT suffers from poor reproducibility with a coefficient of variation (CV) of 17%.[9] In addition, the fasting requirement and two-hour test time make the OGTT clinically inconvenient to administer. The FPG is the most common test for diabetes screening. It is not as sensitive as the OGTT,[9] requiring an overnight fast. A1C has been used for managing glycemia in patients with diagnosed diabetes and has recently been recommended as a diabetes screening test because it does not require fasting and has fewer sources of pre-analytical error than OGTT and FPG.[2] A1C is less sensitive than the OGTT and has equivalent performance to FPG. In addition, ethnic differences in normal A1C levels and analyzer bias can adversely influence the apparent prevalence of abnormal A1C and type 2 diabetes.

The SCOUT DS screens for prediabetes and undiagnosed type 2 diabetes by measuring the fluorescence of the skin due to advanced glycation end products (AGEs) and byproducts of metabolism and oxidative stress. The SCOUT DS measurement does not require fasting, is noninvasive, does not generate biohazards, and does not require any special preparation beforehand. These features make the SCOUT DS well-suited for opportunistic diabetes screening at the point of service.

d. Theory of Operation

SCOUT DS Technology

The SCOUT DS device measures skin fluorescence and reflectance across the near ultra-violet and visible spectrum (360 to 660 nm) to determine a patient's likelihood of having impaired glucose tolerance or undiagnosed type 2 diabetes. The SCOUT DS also uses the

patient's chronological age and gender to compensate for changes that are part of the normal maturation process.

The SCOUT DS does not measure glucose and its corresponding Diabetes Score is not a surrogate for a patient's instantaneous blood glucose concentration. Instead, the SCOUT DS diabetes score is derived from spectral features originating with biomarkers in the epidermis and dermis, which are associated with the progression of diabetes. Among the known spectral biomarkers are fluorescent advanced glycation end products (AGEs) such as pentosidine and crosslines.[10,11] Additional known skin fluorophores include NADH and FAD, which participate in the oxidative phosphorylation process.

Elevated blood glucose is considered a catalyst of diabetes complications. Its deleterious effects are attributable to the formation of sugar-derived substances called advanced glycation end products. AGEs form at a constant but slow rate in normal health, and accumulate with time. AGE formation is markedly accelerated in diabetes because of the increased availability of glucose and oxidative stress due to swings in glucose levels. AGEs are both a participant in the disease and a byproduct of it. AGEs have been shown to be associated with and an independent predictor of the development of retinopathy and nephropathy in persons with diabetes.[12,13,14]

AGEs accumulate in dermal collagen of skin as well as in blood vessels, ligaments, and tendons. Since the half-life of dermal collagen is estimated to be approximately 15 years,[15] AGE levels reflect the accumulation of years of glycemic exposure, oxidative stress and patient-specific glycation rates. This is in contrast to the half-life of A1C, which is approximately 90 to 120 days and dictated by the lifetime of an individual's red blood cells.

In summary, the long-term effects of glucose disregulation, oxidative stress, and patient-specific glycation rates result in a mixture of biomarkers that produce skin fluorescence when excited with near-UV or blue light. In addition, nonfluorescent biomarkers contribute to the SCOUT DS diabetes signal, via wavelength-dependent absorption of the measured fluorescence, thereby imprinting spectral signatures indicative of diabetes-related microvascular damage and skin structural changes. Because the SCOUT DS output indicates the aggregate risk of disease rather than a glucose concentration or the concentration of a single skin AGE, the SCOUT Diabetes Score is not expected to correlate perfectly to any single laboratory analyte. Since the SCOUT DS is insensitive to instantaneous glucose, a patient does not have to fast before a SCOUT DS measurement takes place.

How SCOUT DS Functions

The SCOUT DS illuminates the left volar forearm with low-intensity light at multiple near-ultraviolet and visible wavelengths. A specially designed fiber-optic probe couples the excitation light to the person's forearm and relays resulting skin fluorescence to a detection module. The optical signal is analyzed, adjusting for age, gender, melanin, hemoglobin, and light scattering. In addition, the SCOUT DS uses modeling algorithms based on skin anatomy and skin chemical composition. By combining the intrinsically corrected fluorescent signal with sophisticated multivariate algorithms, the SCOUT DS determines the quality of the measurement—if the quality is sufficient, it produces a SCOUT Diabetes Score (SDS). The SCOUT Diabetes Score is on a scale of 0 to 100 arbitrary units. SCOUT Diabetes Scores above 50 are considered positive for abnormal glucose tolerance, a condition defined as a two-hour, 75 gram oral glucose tolerance test result greater than 7.8 mmol (140 mg/dL), which is considered the lower threshold of impaired glucose tolerance, a prediabetes state of elevated risk for having or developing type 2 diabetes and diabetes related complications.

3. CLINICAL PERFORMANCE SUMMARY

The performance of the SCOUT DS system was validated in two clinical studies, VL-2712 (ENGINE) and VL-2714 (TCOYD).

a. VL-2712 Study Summary

The VL-2712 clinical study was conducted on a cohort of 507 subjects at risk for type 2 diabetes, but without an existing diagnosis of diabetes. The clinical study was carried out at 12 clinical sites distributed across the United States. The trial is registered on www.clinicaltrials.gov (trial ID NCT01080157). Each clinical site had a unique SCOUT DS device.

The demographics of the cohort were as follows:

- Gender: 44% male, 56% female
- Ethnicity: 61% White, 19% Hispanic, 16.5% African American, 3.5% Other
- Age: 19 to 88 years, median age of 53, standard deviation of 13.5 years

The study inclusion criteria were based on the American Diabetes Association guidelines for diabetes screening[2]:

1. Age greater than or equal to 45 years
   or
2. Age 18 to 44 years and a BMI $\geq$ 25 kg/m² with one or more of the following risk factors:
   - Elevated waist circumference > 35 inches for women and > 40 inches for men
   - Habitually physically inactive (does not exercise regularly)
   - Has a first-degree relative with diabetes
   - African American, Latino, Native American, Asian American, Pacific Islander
   - Has delivered a baby weighing > 9 lb or diagnosed with gestational diabetes
   - Hypertension (≥ 130/≥ 85 mmHg) or being treated for hypertension
   - HDL cholesterol level < 35 mg/dL and/or a fasting triglyceride level ≥ 250 mg/dL, or being treated for dyslipidemia with medication
   - Has been previously diagnosed with Polycystic Ovary Syndrome (PCOS)
   - Had impaired glucose tolerance or impaired fasting glucose on previous testing within the last 3 years
   - Conditions associated with insulin resistance such as acanthosis nigricans
   - History of vascular disease including heart attack, stroke, angina, coronary heart disease, atherosclerosis, congestive heart failure, or peripheral arterial disease

The study exclusion criteria were as follows:

- Prior participation in the VL-2701 clinical study
- Receiving investigational treatments in the past 14 days
- Psychosocial issues that interfere with an ability to follow study procedures
- Conditions that cause secondary diabetes including Cushing's syndrome, acromegaly, hemochromatosis, pancreatitis, or cystic fibrosis
- Diagnosed with any type of diabetes, including type 1 or 2
- Taking glucose lowering medications
- Known to be pregnant
- Receiving dialysis or having known renal compromise
- Scars, tattoos, rashes, or other disruption(s)/discoloration(s) on the left volar forearm
- Recent (within past month) or current oral steroid therapy or topical steroids applied to the left forearm; inhaled steroid therapy is not excluded
- Current chemotherapy, or chemotherapy within the past 12 months
- Receiving medications that fluoresce
- Known to have, or at risk for, photosensitivity reactions (e.g., sensitive to ultraviolet light, or taking medication known to cause photosensitivity)
- Prior bariatric surgery

The study procedures were as follows:

Visit 1

Before any study-related procedures were performed, participants were asked to read and sign an informed consent. Participants came to the study center in the morning after fasting (nothing to eat or drink) for at least 8 hours. The following procedures were performed if the subject was eligible for the study and gave informed consent:

- Review of inclusion and exclusion criteria to determine if eligible for study
- A review of medical information
- Examination of LEFT forearm for evidence of scars, wounds, rashes, tattoos, etc. that could interfere with the investigational measurement
- Measurement of height, weight, waist circumference, hip circumference, and blood pressure
- Light measurements of the forearm using the SCOUT DS device. Before SCOUT DS measurements were performed, a small area (2 in x 3 in) may have been shaved if there was thick hair on the underside of the forearm
- Collection of a blood sample (about 1 tbsp) for measurement of fasting blood sugar, A1C, and creatinine
- 75 gram, two hour Oral Glucose Tolerance Test (OGTT)
- Two hours after drinking the glucose solution, another blood sample (about 1 tbsp) was collected

Visit 2

No blood was drawn and the participant did not have to fast prior to this visit (could eat and/or drink as normally would). Second visits occurred in the morning or afternoon, depending on the participant's schedule. The following test was performed on Visit 2.

- Light measurements of the forearm using the SCOUT DS device

The two hour, post challenge plasma glucose of the OGTT performed on Visit 1 was used as the gold standard for determining if a participant had abnormal glucose tolerance (AGT). Abnormal glucose tolerance was defined as a post challenge glucose ≥ 7.8 mmol (140 mg/dL) and encompasses the prediabetes state of impaired glucose tolerance as well as type 2 diabetes. The goal of a diabetes screening test is to rule in subjects that likely have prediabetes or type 2 diabetes. The follow-up diagnostic test then defines the degree of disease (normal, prediabetes, type 2 diabetes). Approximately 25% of the VL-2712 clinical study cohort had AGT, as defined by OGTT.

The abnormal glucose tolerance detection performance of the SCOUT DS measurement was compared to that of the fasting plasma glucose test (the most common and widely accepted diabetes screening test). The primary study hypothesis was that the SCOUT DS partial area under the receiver operator characteristic curve (pAUC), calculated between 20% and 50% false positive rates (clinically relevant range for diabetes screening), was non-inferior to the pAUC of fasting plasma glucose for detection of abnormal glucose tolerance. The non-inferiority margin for the primary hypothesis test was pre-specified as a pAUC difference of 0.027 between the FPG pAUC and the upper 95% confidence limit of the SCOUT pAUC. The pAUC difference was set as twice the standard deviation of the FPG pAUCs for detecting abnormal glucose tolerance in multiple, large clinical studies (NHANES III, NHANES 2005-2006, NHANES 2007-2008, previous VeraLight clinical studies).

In addition to the pAUC metric, the statistical analysis calculated test sensitivity, specificity and false positive rate. Sensitivity is defined as the percentage of AGT subjects that were correctly identified by the test as having AGT. Specificity is defined as the percentage of non-AGT subjects that were correctly identified as not having AGT by the test. False positive rate is equal to 1 – specificity and is defined as the number of subjects that did not have AGT that were incorrectly identified as having AGT.

There are several objective quality control metrics the SCOUT DS applies to each subject measurement to decide if a Diabetes Score should be reported. In VL-2712, 408 participants had SCOUT DS measurements that passed the quality control metrics (13.4% did not have a SCOUT Diabetes Score reported). Potential reasons for failing the quality control metrics include the following:

- Poor contact between participant's forearm and optical probe
- Excessive forearm hair
- Participant moved forearm during measurement

- Participant had sunscreen or lotion applied to forearm and did not inform the clinical study staff before the measurement
- Participant did not complete all study protocol procedures

The 408 participants with reported measurements were used in the statistical analysis, comparing SCOUT DS performance to FPG. The SCOUT DS had a pAUC of 0.202 while fasting plasma glucose had a pAUC of 0.199. The resulting FPG – SCOUT DS pAUC difference was -0.003. The 95% upper confidence limit on the FPG – SCOUT DS pAUC difference was 0.0260, which was less than the pre-specified limit of 0.0270, hence the null hypothesis was rejected and the SCOUT DS achieved the alternative primary study endpoint for effectiveness in that the SCOUT DS is non-inferior to FPG.

During the study, no adverse events--unanticipated or otherwise--were reported nor any safety related events.

At the designated SCOUT DS cut-point of 50 arbitrary units (AU), the SCOUT DS measurement sensitivity (SENS) was 75.2% and the false positive rate (FPR) was 42.1%. The SCOUT DS cut-point was set to have a 40% FPR, based on market input from over 100 physicians; physicians overwhelmingly favored higher test sensitivity at the cost of elevated FPR. The 40% FPR was the most common choice of the surveyed physicians. At the fasting plasma glucose (FPG) cut-point of 5.6 mmol (100 mg/dL), the FPG measurement sensitivity was 56.0% at an FPR of 23.7%, while at a cut-point of 6.1 mmol (110 mg/dL), the FPG measurement sensitivity was 37.6% and the FPR was 7.4%. The SCOUT DS inter-day Hoorn coefficient of variation[9] was 7.7%, while that of FPG was 8.1%. The results are summarized in the following table:

	pAUC (20-50%)	**Cut-Point**	**SENS (%)**	**FPR (%)**	**Hoorn CV (%)**
SCOUT DS	0.202	50.0 AU	75.2 [70.8 – 79.2]	42.1 [37.4 – 47.0]	7.7
FPG	0.199	5.6 mmol	56.0 [51.1 – 60.7]	23.7 [19.9 – 28.1]	8.1
FPG	0.199	6.1 mmol	37.6 [33.1 – 42.4]	7.4 [5.2 – 10.3]	8.1

For reference, in the VL-2712 clinical study for the SCOUT DS, FPG sensitivity and FPR for abnormal glucose tolerance varied as a function of cut-point, as shown in the following table:

SDS Threshold	Sensitivity (%) [95% CI]	False Positive Rate (%) [95% CI]
36	99.1 [97.6 – 99.7]	94.6 [92.0 – 96.4]
38	96.3 [94.0 – 97.8]	91.6 [88.5 – 94.0]
40	95.4 [92.9 – 97.1]	86.3 [82.6 – 89.3]
42	94.5 [91.8 – 96.3]	79.3 [75.1 – 82.9]
44	91.7 [88.7 – 94.0]	70.9 [66.3 – 75.1]
46	86.2 [82.6 – 89.2]	62.2 [57.4 – 66.8]
48	79.8 [75.7 – 83.4]	52.5 [47.7 – 57.3]
50	75.2 [70.8 – 79.2]	42.1 [37.4 – 47.0]
52	66.1 [61.3 – 70.5]	32.8 [28.4 – 37.5]
54	56.9 [52.0 – 61.6]	24.7 [20.8 – 29.2]
56	45.9 [41.1 – 50.7]	17.7 [14.3 – 21.7]
58	37.6 [33.1 – 42.4]	14.4 [11.3 – 18.1]
60	31.2 [26.9 – 35.8]	11.7 [8.9 – 15.2]
62	24.8 [20.8 – 29.2]	9.4 [6.9 – 12.6]
64	18.3 [14.9 – 22.4]	8.4 [6.0 – 11.5]
66	9.2 [6.7 – 12.4]	5.7 [3.8 – 8.4]

The results summarized above indicate that the SCOUT DS provides clinically relevant information for the purposes of screening individuals at risk for prediabetes and type 2 diabetes, and that the performance of the SCOUT DS is non-inferior to that of the FPG test as judged by the partial area under the ROC curve for FPRs between 20% and 50%. In addition, the false positive rate for the SCOUT DS in this prospective clinical dataset was 42.1% (95% CI = 37.4% to 47.0%), which is consistent with the algorithm design target of 40% and with feedback provided to VeraLight in physician surveys.

Based on the clinical relevance of the results and the absence of any safety-related incidents or adverse events, it is concluded that the safety and effectiveness objectives on the VL-2712 trial have been met. The SCOUT DS has been demonstrated to be a safe and effective method for screening individuals at risk for prediabetes and/or type 2 diabetes.

b. VL-2714 Study Summary

The TCOYD study (VL-2714) was a one day, non-significant risk-study executed at the Taking Control of Your Diabetes (TCOYD) conference, held at the San Diego Convention Center on October 30, 2010. The TCOYD study employed 8 identical SCOUT DS devices at the clinical site.

The primary objective of the TCOYD study was to confirm the SCOUT DS sensitivity for detection of type 2 diabetes. A secondary objective was to examine the SCOUT DS case-control performance for detection of type 2 diabetes by combining the type 2 diabetes measurements collected in the TCOYD study, with measurements of subjects with normal glucose tolerance (two hour post-challenge glucose < 7.8 mmol (140 mg/dL)) from the ENGINE study (VL-2712). A third objective was to gain experience with making SCOUT DS measurements at a conference, as it mimics the mobile screening environment, which is a primary market for the SCOUT DS.

All 270 subjects provided informed consent and completed all study procedures on October 30, 2010.

The demographics of the TCOYD cohort were as follows:

- 270 subjects enrolled, 161 females (60%), 109 males (40%)
- 65% diagnosed within last 10 years, 42% diagnosed within last 5 years
- Median A1C of 6.6% ± 1.2%, 66% had A1C ≤ 7.0%
- Age range of 23 to 88 years, median age of 62 ± 11.5 years
- Ethnicity was 56% White, 21% Latino, 9% Asian, 6% African American, 7% Other

The study inclusion criteria were as follows:

- Age greater than or equal to 18 years
- Self-reported diagnosis of type 2 diabetes

The study exclusion criteria were as follows:

- Not diagnosed with type 2 diabetes
- Diagnosed with type 1 diabetes
- Known to be pregnant (self-reported)
- Receiving dialysis or having known renal compromise
- Scars, tattoos, rashes, or other disruption(s)/discoloration(s) on the left volar forearm
- Known to have, or at risk for, photosensitivity reactions (e.g., sensitive to ultraviolet light, or taking medication known to cause photosensitivity)

Subjects arrived at the TCOYD conference study booth any time of day and were not required to fast. Each subject provided informed consent and answered a brief questionnaire to ascertain their age, ethnicity, year of diabetes diagnosis, smoking status, and if they were taking medications for high blood pressure, cholesterol and/or glucose control. Next, the subject's A1C was measured with a Bayer A1C NOW+ analyzer. Finally, the subject was measured on the SCOUT DS. After the SCOUT DS measurement, the subject was informed of his/her A1C result, concluding participation in the trial.

In VL-2714, 222 participants had SCOUT DS measurements that passed the quality control metrics (16.9% did not have a Diabetes Score reported). Potential reasons for failing the quality control metrics include the following:

- Poor contact between participant's forearm and optical probe
- Excessive forearm hair
- Participant moved forearm during measurement
- Participant had sunscreen or lotion applied to forearm and did not inform the clinical study staff before the measurement

The valid-measurement rate for TCOYD was therefore 83.1%.

Because all participants in the TCOYD study were previously diagnosed with type 2 diabetes, there were no disease-negative subjects in the cohort. We therefore report the sensitivity of the SCOUT DS and of the Bayer A1C NOW+ A1C measurements.

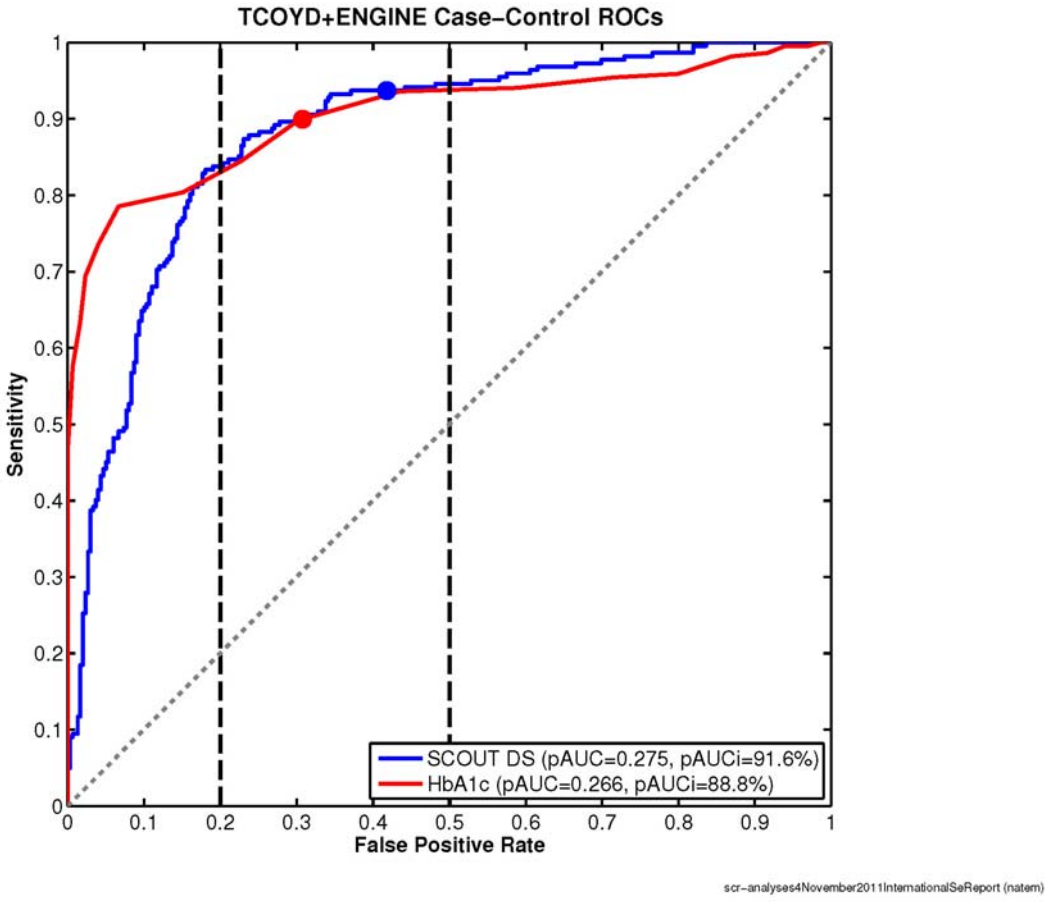
The table below summarizes the distribution of the SCOUT DS (N=222) and A1C (N=222), corresponding to all technically-valid A1C measurements with a related SCOUT DS measurement test result, in addition to the sensitivities and their corresponding 95% confidence intervals.

Test	Median Score [5th 95th] %ile	Screening Threshold	Test Sensitivity at Threshold (%) [95% CI]
SCOUT DS	**64.9 [47.6 – 84.4]**	**SDS = 50**	**93.7 [89.7 – 96.2]**
A1C	**6.6% [5.3 – 9.2]**	**5.7%**	**90.0 [85.3 – 93.3]**

The study results indicate that the SCOUT DS has excellent sensitivity for detection of type 2 diabetes. The SCOUT DS's sensitivity in this population was comparable to that of the Bayer A1C NOW+ meter at the ADA-recommended A1C screening threshold of 5.7%.

To further elucidate the relevance of the clinical data, two exploratory analyses were conducted, merging the TCOYD and ENGINE datasets.

In the first exploratory analysis, the TCOYD data were merged with the data from all technically-valid AGT-negative subjects from the ENGINE study (N=307). The ROC curves for the resulting case-control dataset are depicted in the figure below. Curves are presented for the SCOUT DS and A1C (the only blood reference collected in both studies: laboratory-grade analyzer in ENGINE, point-of-care (Bayer A1C NOW+) in TCOYD).



Case-control ROC curves for the SCOUT DS and A1C computed from a population consisting of all previously-diagnosed Type 2 diabetics completing technically-valid SCOUT DS measurements in the TCOYD study (N=222) and all technically-valid AGT-negative subjects from the ENGINE study (N=307).

In the TCOYD dataset, the sensitivity of the SCOUT DS was comparable to that of the A1C test. At the screening threshold (SDS=50), the SCOUT DS sensitivity for frank diabetes was 93.7%, and the pAUCi (i.e., the average sensitivity for false positive ranging from 20% to 50%) was 91.6%. This pAUCi is comparable to that of the A1C test.

In the second exploratory analysis, the full ENGINE and TCOYD datasets were merged, including all technically-valid AGT-negative, prediabetic, and diabetic subjects. SDS values from the SCOUT DS were then analyzed to determine the relative risks of AGT and diabetes as a function of the SDS threshold. The relative risk analysis is summarized in the table below; relative risks are normalized to the case of a SDS value less than 50.

SDS Range	Relative Risk for AGT	95% CI	Relative Risk for Diabetes	95% CI
SDS < 50	1.0	[0.7 – 1.5]	1.0	[0.6 – 1.8]
50 ≤ SDS < 54	2.0	[1.4 – 3.0]	2.1	[1.2 – 3.9]
54 ≤ SDS < 58	3.2	[2.3 – 4.5]	4.4	[2.7 – 7.1]
58 ≤ SDS < 62	3.9	[2.9 – 5.3]	6.2	[3.9 – 10.0]
62 ≤ SDS < 66	4.3	[3.2 – 5.8]	7.4	[4.7 – 11.6]
66 ≤ SDS	4.5	[3.4 – 6.0]	8.6	[5.6 – 13.2]

Relative risks for abnormal glucose tolerance and for type 2 diabetes for various ranges on the SCOUT DS Diabetes Score.

The above table demonstrates that increasing SDS values convey increasing risk of AGT or type 2 diabetes. For example, an individual with an SDS between 58 and 62 is 3.9 times more likely to have AGT and 6.2 times more likely to have type 2 diabetes than an individual with an SDS less than 50.

The TCOYD dataset provides further evidence that the SCOUT DS is a safe and effective method for screening individuals at risk for prediabetes and type 2 diabetes.

Specifically, the TCOYD results provide confidence that individuals with type 2 diabetes will be identified reliably by the SCOUT DS.

In addition, the exploratory analysis of the relative risks of AGT or frank diabetes associated with the SCOUT DS Diabetes Scores indicate that the risk of disease increases with increasing SDS. These findings allow for better interpretation of a given SCOUT DS measurement.

4. WARNINGS, CAUTIONS, CONTRAINDICATIONS, AND SAFETY

a. Warnings

SKIN PHOTOSENSITIVITY

⚠ **Warning:** Do not use the SCOUT DS on individuals known to have, or be at risk for, photosensitivity reactions (e.g., sensitivity to ultraviolet light, or taking medication known to cause photosensitivity).

ELECTRICAL SAFETY

The SCOUT DS is designed to be safe from electrical shock when operated according to instructions. It uses a medical grade, external power supply. All conductive parts of the chassis, including the optical probe and data signal panel at the rear of the unit, are either protectively grounded or are isolated from the power supply. However, please keep in mind that there are some limitations with regard to electrical safety. These are:

⚠ **Warning:** The SCOUT DS is not intended to be operated near life-support equipment.

⚠ **Warning:** Do not connect any device to the SCOUT DS device's USB receptacles unless directed to do so by VeraLight; doing so may result in an electrical hazard or device malfunction.

⚠ **Warning:** To avoid the risk of electric shock, the SCOUT DS device must be connected to supply mains with protective earth.

 Class I Equipment, Type BF Applied Part

⚠ **Warning:** MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual (see Section 4D and Appendix A).

⚠ **Warning:** Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

⚠ **Warning:** The use of accessories, transducers, and cables other than those specified by VeraLight, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT.

⚠ **Warning:** This EQUIPMENT should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the EQUIPMENT should be observed to verify normal operation in the configuration in which it will be used.

⚠ **Warning:** The SCOUT DS is not fully compliant to 2002/95/EC, RoHS. If disposal is required for any reason, please return unit directly to the manufacturer or to the Authorized Representative identified on the SCOUT DS product label. Disposal in any other manner poses a risk to the environment.

b. Cautions

CAUTION: This device cannot rule out DM type 2 and prediabetic states, especially new/acute onset.

CAUTION: To eliminate any risk of eye injury, do not stare at the light while the Sensor is uncovered.

CAUTION: Not following the cleaning procedure (using a dry wipe after using a wet wipe) increases the risk of an allergic reaction to the cleaning solution.

CAUTION: There is the possibility that in patients with the following conditions, an inaccurate measurement might occur:

- Onset (type 1) diabetes mellitus
- Pregnancy where the woman is unaware
- Acutely ill patients
- Patients in an acute state such as ketoacidosis or hyperosmolar nonkinetic coma
- Patients with diabetes undergoing surgery

CAUTION: Medical staff using the SCOUT DS should receive training regarding its use.

CAUTION: Because of the cumulative effect of exposure to light energy, it is not recommended to perform more than thirty (30) complete screening measurements within a 24-hour period on any given patient.

ARM HAIR

If the person has a large amount of hair on the volar forearm, the area must be shaved with a safety razor and shaving cream, then rinsed thoroughly with water

and patted dry. Failure to shave forearms with significant hair may render the person not measurable by the SCOUT DS.

SUNSCREEN and LOTION

Lotion or sunscreen on the left volar forearm will interfere with the measurement and the operator will be notified that the person is not measurable. When this occurs, wash the volar forearm with mild soap and pat dry. Then repeat the measurement. Always inquire about the application of lotions or sunscreen on the left forearm prior to the procedure.

TATTOOS

Tattoo(s) on the left volar forearm may interfere with the measurement and the operator will be notified that the person is not measurable.

SKIN RASHES

A rash on the left volar forearm may interfere with the measurement and the operator will be notified that the person is not measurable.

PROPER CHAIR and TABLE HEIGHT

Best results are achieved with the person seated during the measurement. Accurate measurements with the SCOUT DS are facilitated by the proper distance between the person, chair, and the SCOUT DS tabletop. The SCOUT DS tabletop should be 13 to 18 cm (5 to 7 in) higher than the seat of the person's chair to maintain the optimum arm angles for the measurement (see Section 7 for details).

c. Contraindications

The SCOUT DS is not indicated for diabetes screening of individuals that fall into one or more of the following categories:

- Known to have, or at risk for, photosensitivity reactions (e.g., sensitive to ultraviolet light, or taking medication known to cause photosensitivity)
- The SCOUT DS is not designed for use on persons with type 1 diabetes
- The SCOUT DS is not designed for use on women who are pregnant
- The SCOUT DS has not been evaluated for diabetes screening effectiveness in persons younger than 18 years
- Taking glucose lowering medications
- Receiving dialysis or having known renal compromise

- Recent (within past month) or current oral steroid therapy or topical steroids applied to the left forearm; inhaled steroid therapy is not excluded
- Current chemotherapy, or chemotherapy within the past 12 months
- Receiving medications that fluoresce
- Prior bariatric surgery

d. Safety

The measurement of skin fluorescence by the SCOUT DS, using UV exposure from the instrument, is less than that routinely encountered from exposure to sunlight for two minutes. As shown in the table, the radiation emitted by the SCOUT DS is well below the Threshold Limit Values (TLVs) promulgated by the American Conference of Governmental Industrial Hygienists (ACGIH) when applied to assess potential skin exposure effects. There is no eye safety hazard if the SCOUT DS is used per its labeling. Light emission occurs when the person's arm covers the Sensor and during the calibration checks when the Calibration Cap is on the Sensor.

The SCOUT DS Light Energy Output and Threshold Limit Values

Wavelength (nm)	SCOUT DS Radiant Exposure (J/m^2)	TLV (J/m^2)	SCOUT/TLV (%)
375	3.2×10^3	3.9×10^5	0.8
405	4.4×10^3	1.0×10^6	0.4

The SCOUT DS carries an Edison Testing Laboratories (ETL) mark signifying that it passed rigorous electrical safety testing and conforms to the safety standards shown below:

Medical Electrical Equipment: Part 1: General Requirements for Safety – UL 60601-1 (1st Ed.; 25-Apr-03, Rev 26-Apr-06).

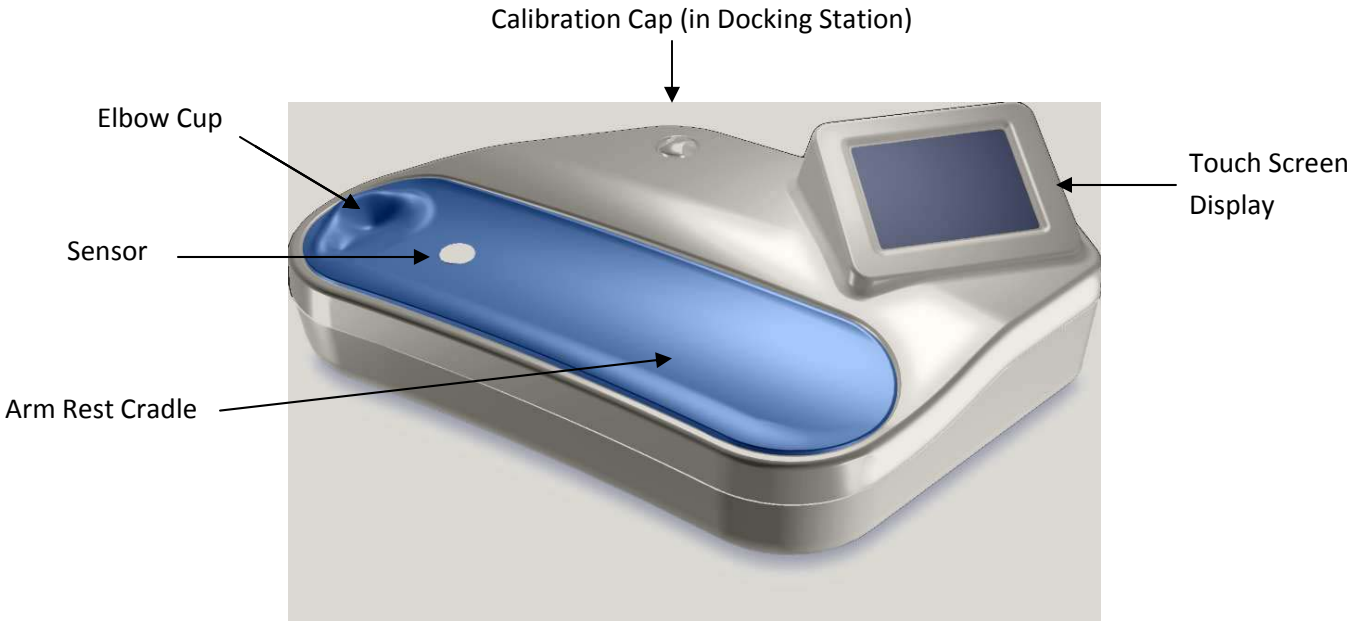
Medical Electrical Equipment: Part 1: General Requirements for Safety – General Instruction No. 1 – CAN/CSA C22.2 601.1-M90 (1st Ed.; Nov-90, R2005) + Supplement No. 1-94 (C22.2 No. 601.1S1-94, Feb-94, R1999) + Amendment 2; 1998 (Feb-98, R2006) + Update No. 2 (Nov-03, R2005).

Canadian Class II Licence Number: 85875

5. DESCRIPTION OF THE SCOUT DS® DEVICE

a. SCOUT DS

The SCOUT DS uses fluorescence spectroscopy to noninvasively measure advanced glycation end products (AGEs) plus markers of oxidative stress and metabolism in the skin. AGEs are known biomarkers of diabetes. The device illuminates the left volar forearm skin with low-intensity light at multiple near-ultraviolet and visible wavelengths. A specially designed fiber-optic probe couples the excitation light to the person's forearm and relays the resulting skin reflectance and fluorescence to a spectrograph and camera. The optical signal is then analyzed for fluorescence related to the development of diabetes, after adjusting for age, gender, skin color, hemoglobin, and other skin characteristics.



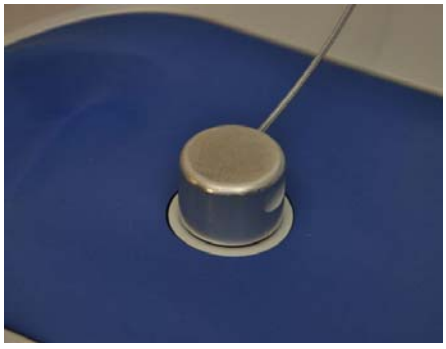
Major Components of the SCOUT DS Device

b. Calibration Cap

The SCOUT DS device uses a factory-calibrated reference called the “Calibration Cap” that sits on top of the Sensor and reflects light back to the spectrograph and camera during illumination. The tethered Calibration Cap is a cylindrical device with three balls on the bottom.

Side and Bottom Views of Calibration Cap

The SCOUT DS device compares the reflected light to previous measurements with the same reference standard. Differences between reference measurements are then used to correct associated person measurements. In addition, reference measurements allow the device to check for component malfunctions. The Calibration Cap should be seated on the Sensor when not taking a measurement, or resting in its Docking Station when taking a measurement.



Calibration Cap Seated on Sensor

When the SCOUT DS system is turned on with the Calibration Cap in place over the Sensor, it will run a self-calibration. It will also run periodic self-calibrations during normal operation. After the calibration is complete and you are ready to measure a person, remove the Calibration Cap and place in its Docking Station.

It is okay to delay the SCOUT DS countdown to the next calibration in order to measure a person.

NOTE: Never wipe or attempt to clean the Calibration Cap.

NOTE: Always place the Calibration Cap on the Sensor when not measuring a person.

c. Touch Screen

The SCOUT DS touch screen display is the main control and information interface, providing step-by-step instructions to the operator during a measurement. The operator initiates measurements and monitors measurement progress using the touch screen, with measurement results reported on the touch screen. In addition, loading more tests, device configuration, and device shutdown as well as review of measurement, calibration, and event histories are completed via the touch screen display.

d. Tests

The SCOUT DS device must be loaded with screening tests before a measurement can start and complete. Tests are added to the SCOUT DS by entering a 30-character Test Key Code via the touch screen display. For each successful measurement, the test count will decrement by one. If a measurement is unsuccessful, the test count will not be decremented. If the test count falls to zero, no measurements can be performed until the device is loaded with additional tests. The device may be loaded with additional tests at any time.

e. Power Supply

The SCOUT DS device is powered by a medical grade, external AC to DC Power Supply. The Power Supply must be connected to a single phase AC power outlet. The DIN connector of the Power Supply is connected to the back panel of the SCOUT DS to provide the DC power required by the device.

6. SPECIFICATIONS

a. Power

The power supply requires one standard, grounded, electrical outlet with the following characteristics:

- 100 – 240 VAC
- 47 – 63 Hz
- 2.0 A minimum

b. Environmental

OPERATION

The SCOUT DS should be operated at ambient temperatures between 18° C and 30° C (64^{o} F to 86^{o} F) at no more than 85% Relative Humidity (non-condensing).

STORAGE

The SCOUT DS should be stored (including shipping environment) at temperatures between -29° C and +60° C (-20^{o} F to 140^{o} F) at no more than 85% Relative Humidity (non-condensing).

RoHS COMPLIANCE

The SCOUT DS is not fully compliant to 2002/95/EC, RoHS. If disposal is required for any reason, please return unit directly to the manufacturer or to the Authorized Representative identified on the SCOUT DS product label. Disposal in any other manner poses a risk to the environment.

c. Physical

Height = 20 cm (8 in)

Length = 55 cm (22 in)

Width = 40 cm (16 in)

Weight = 5 kg (11 lbs)

7. SETTING UP THE SCOUT DS® DEVICE

1. **Place the SCOUT DS device on a sturdy table** with a smooth surface, approximately 61 cm (24 in) high. Do not place the device in sunlight or directly under bright light.

2. **Place a standard height, firm-backed chair**, without swivels or wheels and with its seat 46 cm (18 in) from the floor, next to the table**.** To help you better set up the device, see the two photos below illustrating how a person should be positioned for measurements.

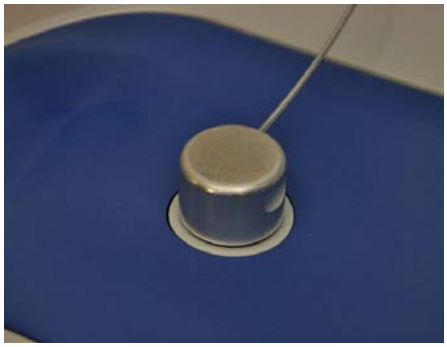
Positioning of Person and the SCOUT DS Device

3. **Clean the Sensor** with the VeraLight supplied wet and dry wipes.

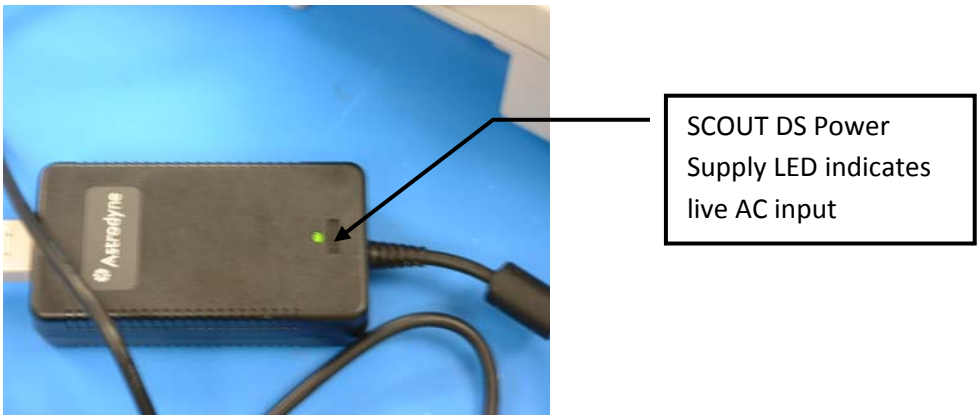
   Note: Other wipes or solutions may damage the Sensor and adversely affect the SCOUT DS measurement. Abrasive wipes such as paper towels, facial tissue (Kleenex®), and toilet paper should never be used to clean the Sensor.

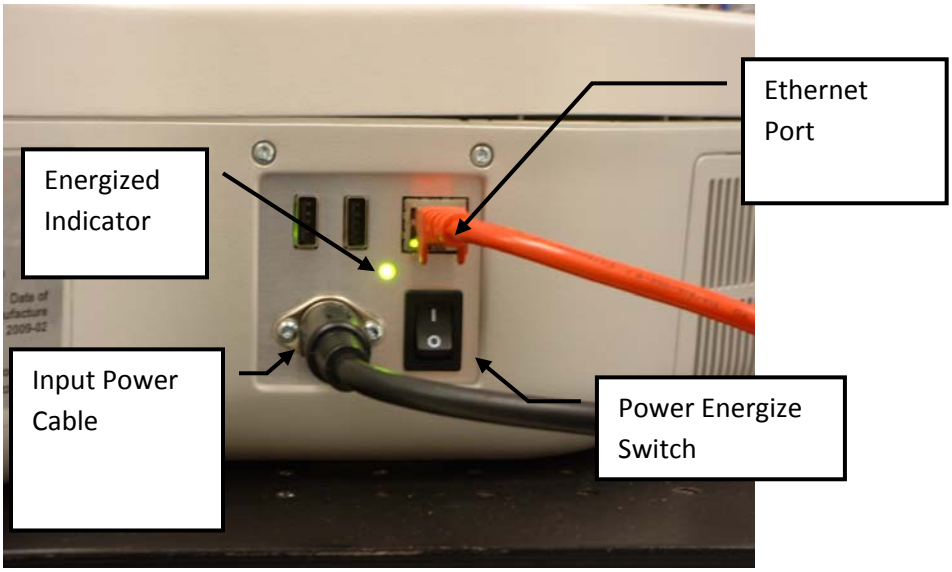
   Clean the Sensor when you first setup the device and then *after* EACH measurement of a person. Gently wipe the Sensor surface with the supplied moist wipe using several circular motions. Then immediately wipe the surface using the supplied dry wipe Motions should be circular to clean the surface, avoiding streaking and spotting. Check for lint, hair, dust, or residue on Sensor.

4. **Place the Calibration Cap on the Sensor.**



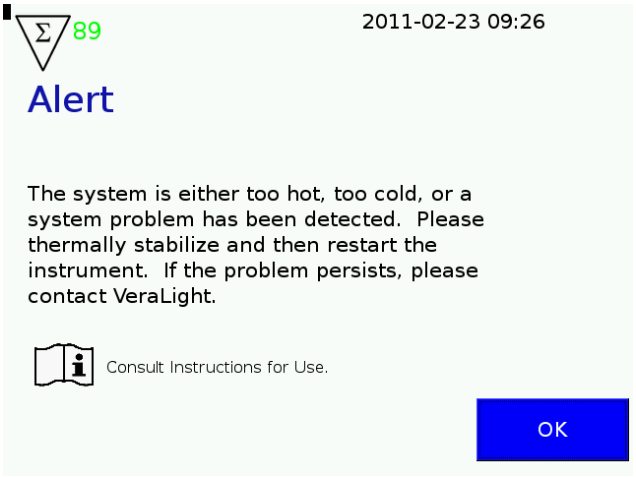
5. **Connect the black cable from the Power Supply to the back panel of the SCOUT DS. Next connect the AC power cord to the power supply. Then plug the AC power cord into a single phase, AC outlet.**



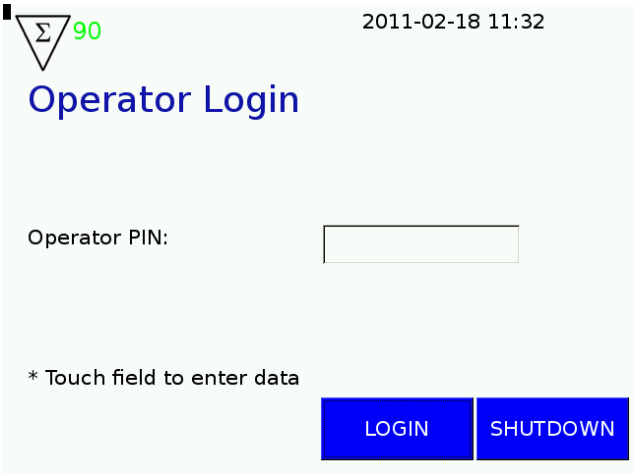


6. **Push the rocker switch at the back of the device to ON (up position).** It will take 5 or 6 minutes to start up. You will see multiple screen changes as the device runs through its sequencing. Ignore the screens until you see the Operator Login screen.

   Note: If the device is too cold (less than 15 °C/59 °F) or too hot (greater than 33 °C/91 °F) due to shipping or storage conditions, allow it to come to room temperature by turning it on and letting it run for approximately 60 minutes. You may get the following alert screen if this is the case.



7. On the Operator Login screen, press the Operator PIN box.

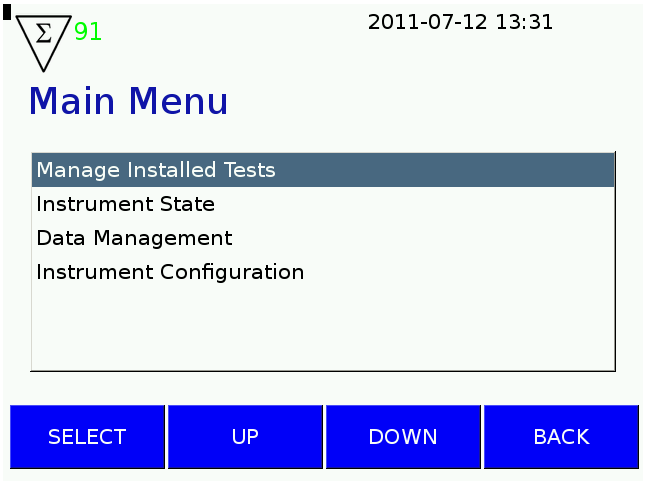


8. A keypad will appear on the screen. Enter **1234567** or the Operator PIN established in the SCOUT DS Instrument Settings, then press the enter button (↵) or press DONE. If you wish to return to the LOGIN screen without entering a PIN, press CANCEL.

9. The Operator Login screen shown in step 7 will reappear with the dialog box filled in. Press **LOGIN.** If the Operator PIN was entered correctly, the **TEST SETUP** screen will appear and you can initiate measurements.

8. ADDING TESTS

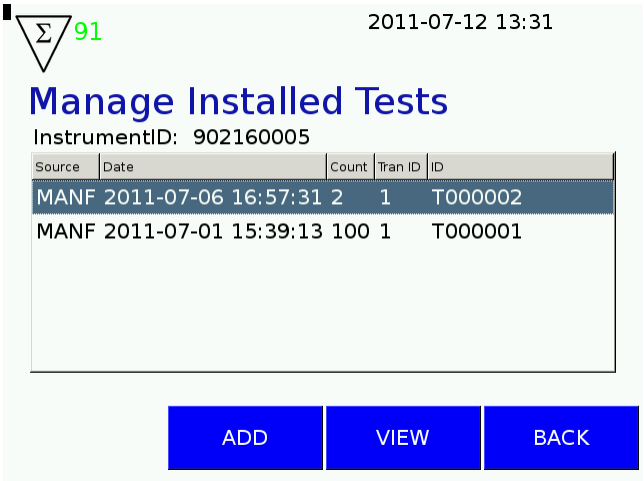
To add tests to the SCOUT DS device, you must first access the **Main Menu** screen by pushing MENU on the Test Setup screen. The **Main Menu** provides access to the **Manage Installed Tests** sub-menu, as shown in the figure below:



Highlight the **Manage Installed Tests** by touching the screen over the sub-menu title or using UP/DOWN, then press SELECT to enter the highlighted sub-menu. To return to the **Test Setup** screen from the **Main Menu** screen, press BACK.

Manage Installed Tests

The **Manage Installed Tests** sub-menu (shown below) allows you to view installed test keys and add new Test Key Codes. Test Key Codes are purchased from VeraLight or its distributors and each Test Key Code authorizes a specified number of new tests. Test Key Codes are specific to each SCOUT DS device and the device serial number must be provided to VeraLight or your distributor before a new Test Key Code can be created.



You can view details for an installed Test Key Code by highlighting the particular test key entry and then pressing VIEW. Press BACK when done viewing details.

To load additional tests on your SCOUT DS using a Test Key Code, press ADD to bring up the screen below:

Enter the 30-character test authorization code using the touch screen keyboard and then press DONE.

To return to the **Main Menu** screen from the **Manage Installed Tests** sub-menu, press BACK.

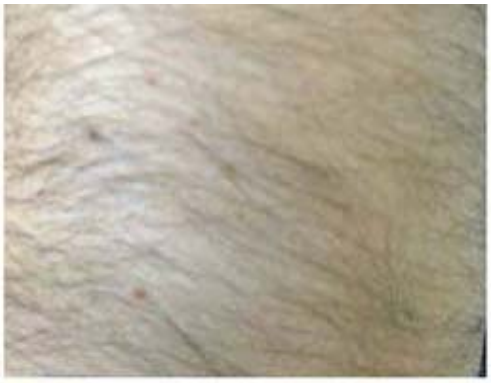
NOTE: To purchase a new Test Key Code, please contact your VeraLight distributor or call VeraLight sales at 505-272-7023, or send an email request to customerservice@veralight.com.

9. MAKING A MEASUREMENT

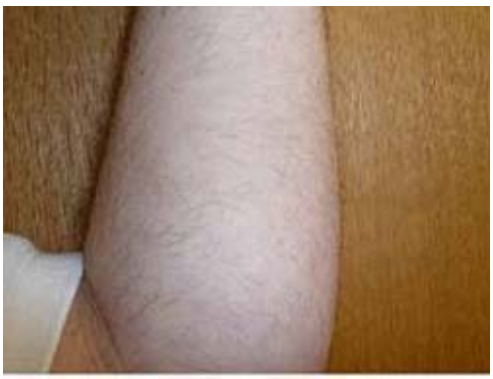
STEP 1. **Before running a test, check the person's left forearm for lotions, rashes, tattoos, and excess hair.** Ask person if there are any lotions or sunscreen on the arm. If so, wash with mild soap and room temperature water; pat dry gently.

If the forearm area that will fall over the Sensor requires shaving, use either shaving cream and a safety razor or an electric razor to remove excess hair from that area of the forearm. Do not use chemical hair removal products. After shaving, rinse and pat dry.

Note: Do not use chemical hair removal products.



☑ Shave

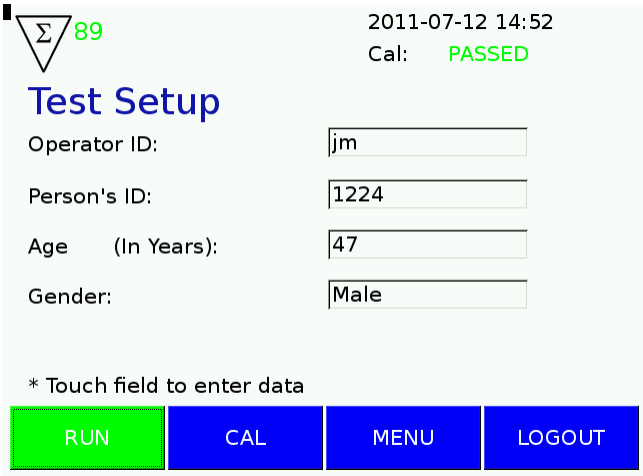


☒ Don't Shave

Degree of Hair in Volar Forearm Area

If there is a birthmark, tattoo, skin rash, other skin discoloration(s) or disruption(s) that will be over the Sensor, the measurement should not be performed.

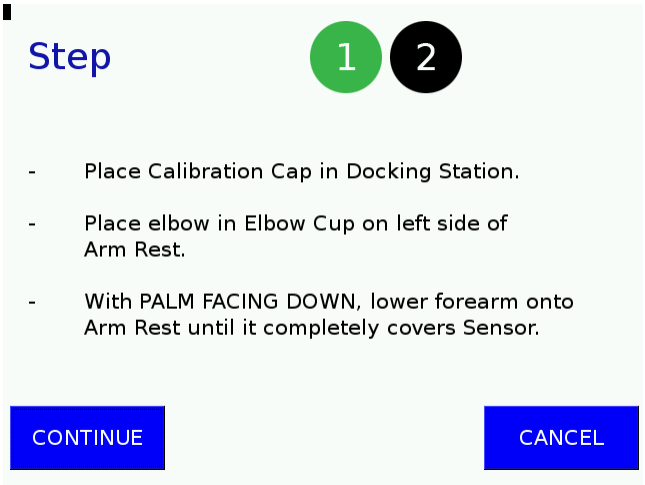
STEP 2. **On the TEST SETUP screen, press the Operator Name box. A keypad will appear on the screen. Enter Operator Name** then press the enter button (↵). **Enter Patient Age** and **Patient ID** by pressing the respective boxes. For each box, enter the appropriate data using the keypad in the same manner as done for the Operator Name. **Patient IDs** are an alpha-numeric identifier, whose format is determined by individual customer requirements. Finally, enter the **Patient Gender** by pressing that box and selecting male or female.



STEP 3. **Press RUN.**

STEP 4. **Confirm the person's age/gender** by pressing **YES** (or **CANCEL** to go back and change).

STEP 5. **A message will appear with instructions to place the Calibration Cap in its Docking Station and to have the person place their forearm on the SCOUT DS. Position the person's left arm carefully on the device.** The forearm should be bare, with no heavy jewelry. Any fabric should be pulled above the elbow. Place the person's left elbow into the Elbow Cup and then lower the forearm with the palm facing down, maintaining elbow position. The person should continue to rest the arm lightly and not apply pressure. Check that the arm completely covers the Sensor and no metal is visible.



Correct **Incorrect**

Forearm Covering Sensor

- If the person has a thin forearm it may sometimes be necessary to reposition the arm slightly toward the person in order to fully cover the Sensor.

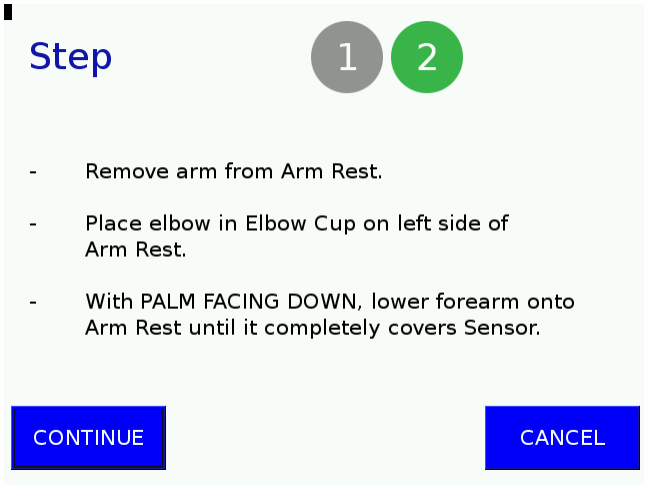
NOTE: The arm should be relaxed and motionless during the measurement.

Press CONTINUE.

While the 1st measurement insertion is underway, the progress is displayed on the screen, as shown.

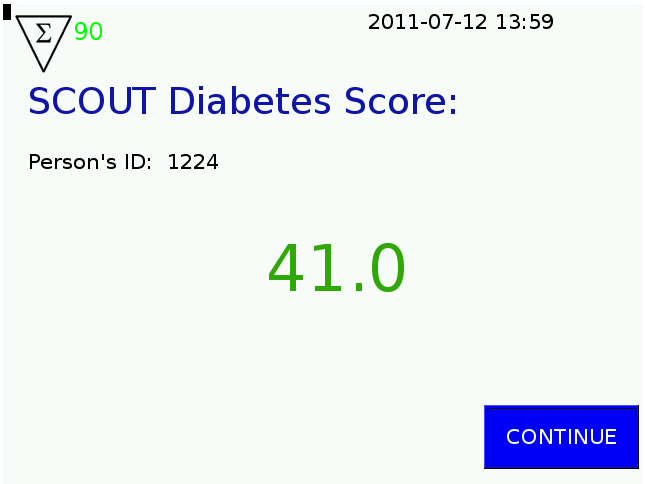
At the end of the first measurement insertion (~1 min), the SCOUT DS will instruct you to have the person lift his/her forearm and press CONTINUE, as shown below.

STEP 6. **Have the person remove his/her arm from the Arm Rest, and then return the elbow, arm, and palm to the Arm Rest. Press CONTINUE.**

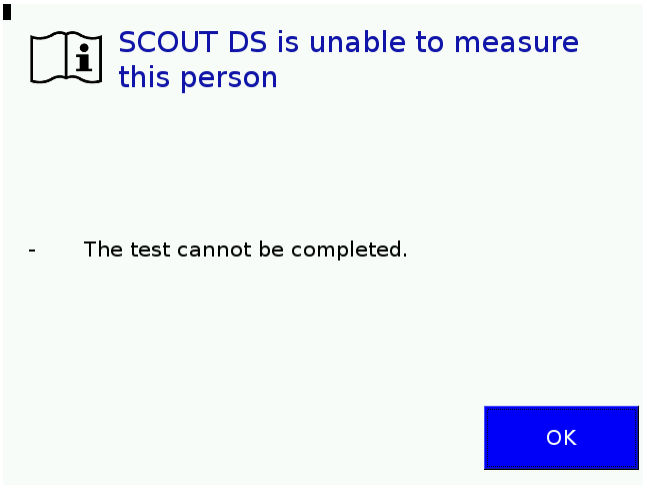


The second measurement insertion will commence automatically and the following progress screen will appear.

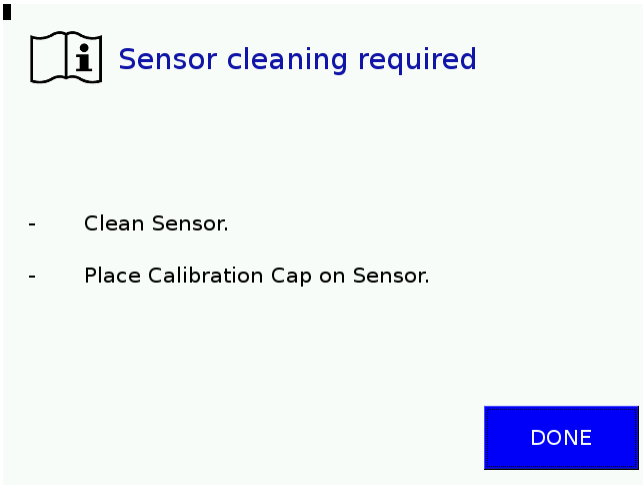
STEP 7. **If the measurement passes the quality control checks, a SCOUT Diabetes Score will be reported as shown below. Record the SCOUT Diabetes Score in the patient chart. Press DONE to move to the cleaning step.**

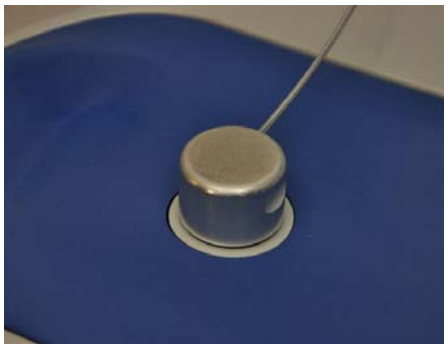


If the quality control checks are not passed, the following screen will appear. Press OK to move to the cleaning step. You can retry the measurement on the person if desired.



STEP 8. **Clean the Sensor with approved wet and dry wipes and then place the Calibration Cap over the Sensor.**





Press DONE once the Calibration Cap is properly seated on the Sensor. The SCOUT DS will return to the Test Setup screen.

10. INTERPRETING RESULTS

Successful SCOUT DS measurements report a SCOUT Diabetes Score (SDS) on a scale of 0 to 100. Measurements that result in Scores of 50.0 or greater indicate that the person is likely to have either prediabetes or diabetes and a follow-up blood test should be performed by the health care provider in order to make that diagnostic determination.

SCOUT DS Measurement	Screening Designation	Recommended Clinical Action
SDS ≤ 49.9	Negative	Rescreen in 1 or 3 years depending on risk factors
SDS ≥ 50.0	Positive	Perform follow-up blood test (OGTT, FPG, or A1C) to make diagnosis (normal, prediabetes, diabetes)

In general, the higher the SCOUT Diabetes Score is above 50, the more likely the person has diabetes instead of prediabetes, based upon merger of clinical study data from validation studies VL-2712 (ENGINE) and VL-2714 (TCOYD):

SDS Range	Relative Risk for AGT	95% CI	Relative Risk for Diabetes	95% CI
SDS < 50	1.0	[0.7 – 1.5]	1.0	[0.6 – 1.8]
50 ≤ SDS < 54	2.0	[1.4 – 3.0]	2.1	[1.2 – 3.9]
54 ≤ SDS < 58	3.2	[2.3 – 4.5]	4.4	[2.7 – 7.1]
58 ≤ SDS < 62	3.9	[2.9 – 5.3]	6.2	[3.9 – 10.0]
62 ≤ SDS < 66	4.3	[3.2 – 5.8]	7.4	[4.7 – 11.6]
66 ≤ SDS	4.5	[3.4 – 6.0]	8.6	[5.6 – 13.2]

A positive SCOUT DS result should be followed up with a CDA/ADA/WHO[1,2,3] recommended blood test for diabetes diagnosis. These blood tests include a two hour, 75 gm oral glucose tolerance test (OGTT), fasting plasma glucose (FPG), or A1C.

An OGTT is recommended as the follow-up diagnostic test if a person's SCOUT Diabetes Score is ≥ 50. The OGTT is the most sensitive of the diabetes diagnostic tests, providing information about the fasting glucose as well as the two-hour post-challenge glucose. It presents a more complete picture of whether the person has isolated post-prandial hyperglycemia, isolated fasting hyperglycemia, or both conditions.

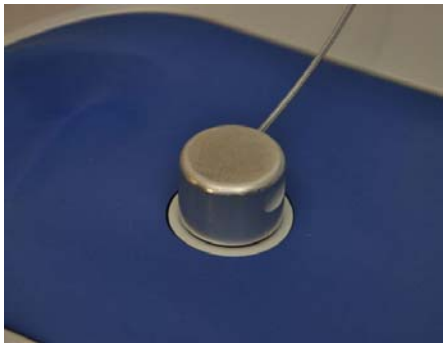
FPG or A1C can also be used as follow-up diagnostic tests. While FPG and A1C are more convenient than the OGTT, they suffer from poor sensitivity and may actually miss persons with isolated post-prandial hyperglycemia.

11. QUALITY CONTROL

The SCOUT DS has a number of built-in quality checks to ensure that the device is operating properly and that reported measurements are accurate.

a. Device Operation

Upon power-up, the SCOUT DS automatically runs a calibration check as part of device initialization. The Calibration Cap must be placed on the Sensor and properly seated before the device is turned on, as illustrated in the figure below:

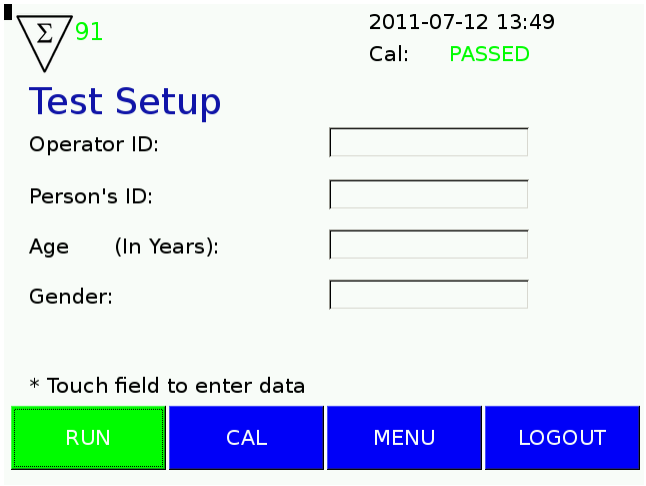


Calibration Cap Seated on Sensor

Users can manually initiate a calibration check from the Test Setup screen whenever a person is not being measured, by performing the following steps:

STEP 1: Make sure the Calibration Cap is placed on the Sensor and is properly seated.

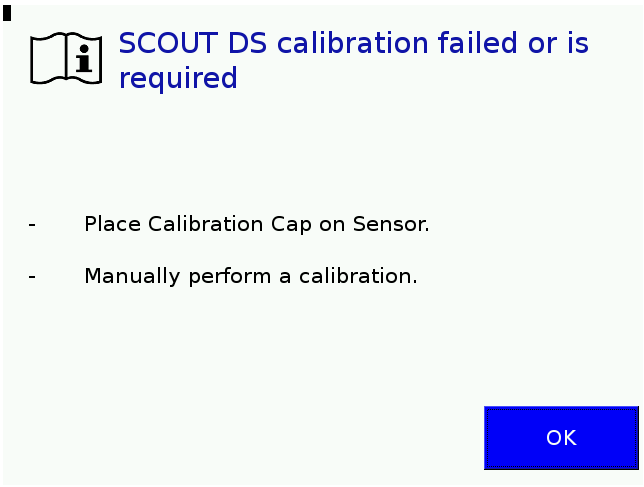
STEP 2: From the **Test Setup** screen on the touch screen, press CAL.



The calibration check will start and the **Calibration Progress** screen will appear.

STEP 3A: When the calibration check is complete, the **Calibration Result** screen will appear (see figure below) with a message that the calibration check passed. Press DONE on the **Calibration Result** screen. The device will return to the **Test Setup** screen. The SCOUT DS is now ready to perform measurements.

STEP 3B: If the calibration check fails, an **Alert** screen will appear (see figure) stating the failure. Press OK to return to the Test Setup screen and retry the calibration check after ensuring the Sensor is clean and the Calibration Cap is properly seated on the Sensor. If the device repeatedly fails the calibration check, please contact your VeraLight Distributor or VeraLight technical support via phone at 505-272-7023, or email customerservice@veralight.com.



NOTE: Measurements are not allowed until the device passes the calibration check.

b. Measurements

The SCOUT DS performs numerous quality checks during a measurement to ensure that only accurate results are reported. Common problems include:

- Room lights contaminating the optical measurement
- Calibration standard on Sensor instead of person's forearm
- Person's forearm not on, partially covering, or otherwise improperly placed on Sensor
- Excessive hair on area of forearm in contact with Sensor
- Shirt sleeve not sufficiently rolled up
- Person moves forearm during measurement
- Person has tattoo, sunscreen, or lotion on area of forearm in contact with Sensor
- Rash, cut, or other skin disruption on area of forearm in contact with Sensor
- Insertion 1 and insertion 2 of person's forearm not consistent
- Person has porphyria or psoriasis that interferes with measurement
- Insufficient fluorescence detected from person's forearm

If one of these conditions is detected, an **Alert** message screen will be displayed on the touch screen and the device will request that the person's forearm be reinserted onto the Sensor and Arm Rest. A maximum of 3 retries per insertion are possible, after which the measurement will be aborted and the device will return to the **Test Setup** screen.

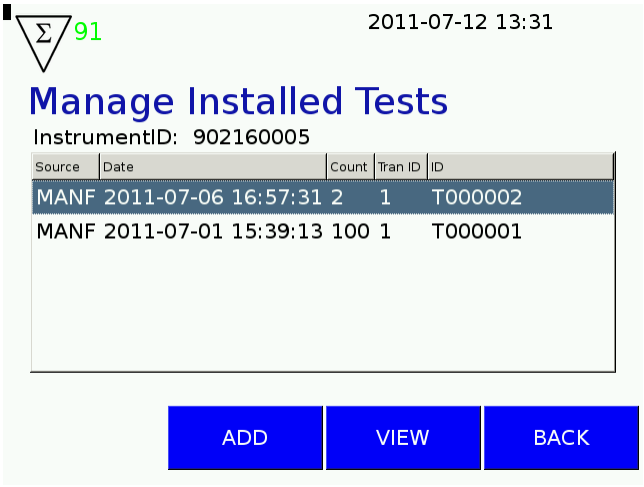
12. MAIN MENU AND EXPORTING DATA

The **Main Menu** screen is accessed from the Test Setup screen by pushing MENU. The **Main Menu** provides access to the following sub-menus, as shown in the figure below:

To access a sub-menu, highlight the desired sub-menu by touching the screen over the sub-menu title or using UP/DOWN, then press SELECT to enter the highlighted sub-menu. To return to the **Test Setup** screen from the **Main Menu** screen, press BACK.

a. Manage Installed Tests

The **Manage Installed Tests** sub-menu (shown below) allows you to view installed test keys and add new Test Keys Codes. Test Key Codes are purchased from VeraLight or its distributors and each Test Key Code authorizes a specified number of new tests. Test Key Codes are specific to each SCOUT DS device and the device serial number must be provided to your distributor or VeraLight before a new Test Key Code can be created.



You can view details for an installed Test Key Code by highlighting the particular Test Key Code entry and then pressing VIEW. Press BACK when done viewing details.

To load tests on your SCOUT DS using a Test Key Code, press ADD:

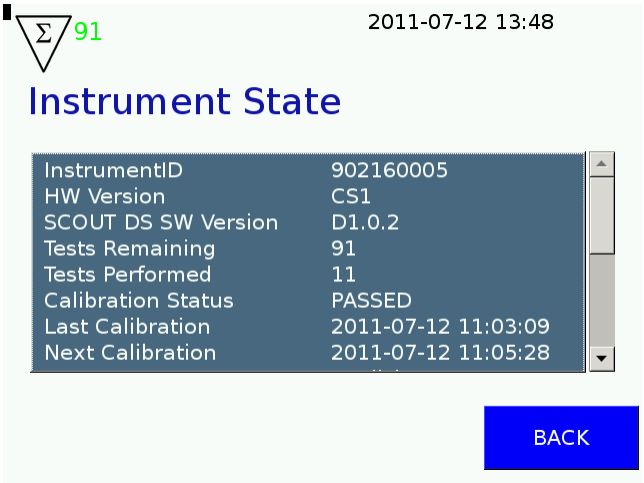
Enter the 30-character Test Key Code using the keyboard and then press DONE.

To return to the **Main Menu** screen from the **Manage Installed Tests** sub-menu, press BACK.

NOTE: To purchase a new Test Key Code, please contact your VeraLight distributor or call VeraLight sales at 505-272-7023, or send an email request to customerservice@veralight.com.

b. Instrument State

The Instrument State sub-menu (shown below) contains status and configuration information for your SCOUT DS device.



You can scroll up or down by touching the scroll bar on the right of the screen and dragging up or down. The following items are displayed in this sub-menu:

- MAC Address – Ethernet physical address
- IP Address – Assigned internet address

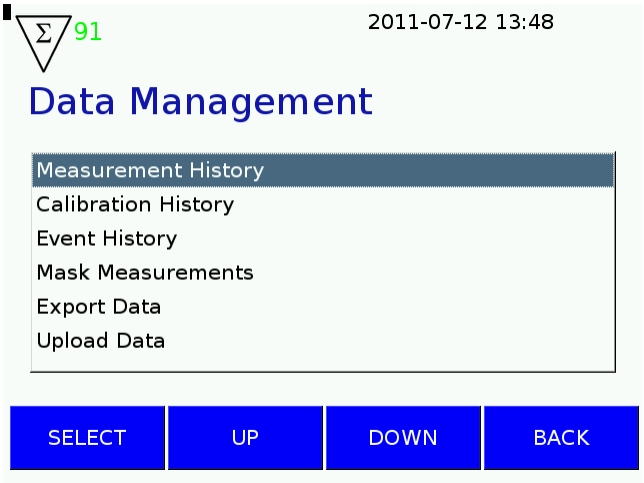
- HW Version – SCOUT DS hardware version
- Scout SW Version – SCOUT DS software revision
- Firmware Version – SCOUT DS firmware revision
- Cam FW Version – SCOUT DS camera firmware revision
- Cam HW Version – SCOUT DS camera hardware version
- Cam Driver Version – SCOUT DS camera device driver revision
- Language – SCOUT DS operator interface language
- Instrument ID – SCOUT DS device serial number (needed to order new test keys)
- Tests Remaining – Number of authorized tests left before more must be added
- Tests Performed – Number of tests made on this SCOUT DS
- Calibration Status – Success of last calibration check
- Last Calibration – Time and date of last calibration check
- Next Calibration – Time and date on next scheduled automated calibration check
- Algorithm Version – SCOUT DS measurement algorithm revision

When purchasing additional Test Key Codes, you can quickly find the device serial number by accessing the **Instrument State** sub-menu.

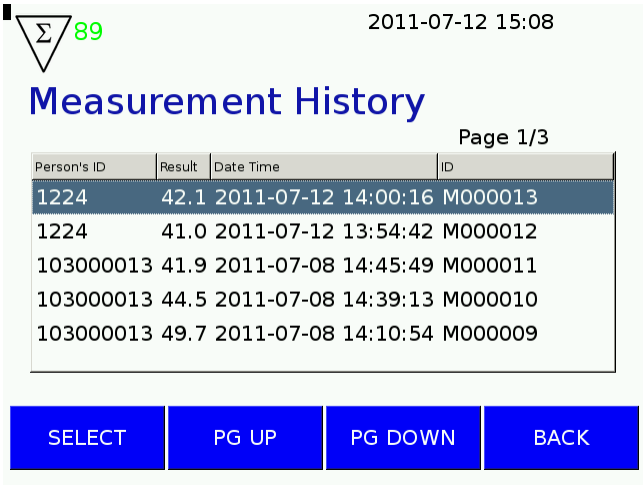
In addition, if you are having issues with your SCOUT DS, VeraLight technical support may ask you for information found on the **Instrument State** sub-menu.

c. Data Management

The **Data Management** sub-menu (shown below) provides access to various data functions, including permanently masking patient measurements, exporting patient measurements or support data, and viewing histories of patient measurements, calibration checks, and instrument events. For clinical trials, the **Data Management** sub-menu also supports immediate uploading of clinical study files via the internet.

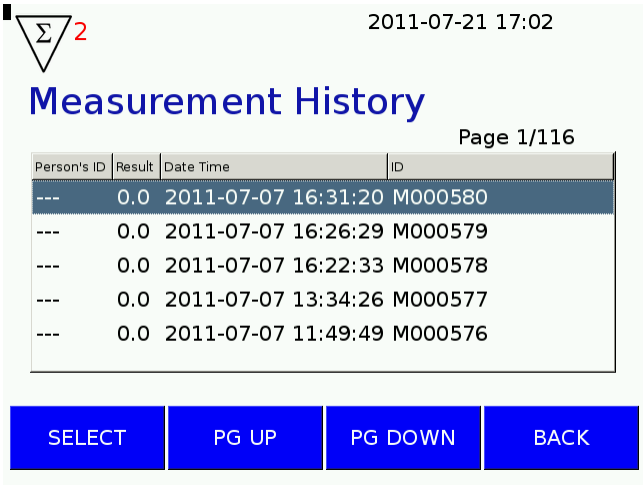


The **Measurement History** sub-menu (shown below) contains a history of the last 10,000 measurements made on your SCOUT DS device.

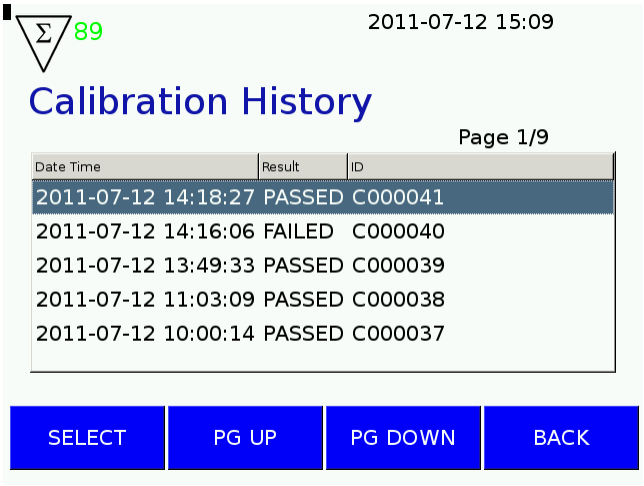


Press the PG UP and PG DOWN to scroll through the measurements. Details of a particular measurement can be displayed by highlighting the measurement of interest by pressing the touch screen and then pressing SELECT. Press BACK to return to the **Main Menu** screen.

If the measurements have been masked (via the **Mask Measurements** option), the **Measurement History** sub-menu will appear as shown for all measurements taken prior to the last **Mask Measurements** command.

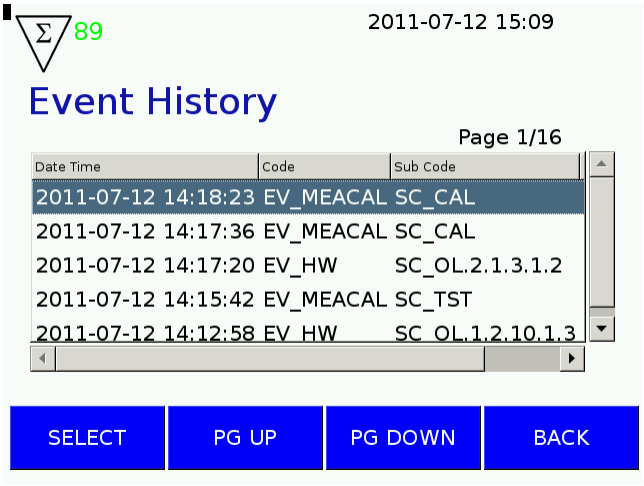


The **Calibration History** sub-menu (shown below) contains a history of the last 10,000 calibration checks made on your SCOUT DS device.



Press PG UP and PG DOWN to scroll through and view the calibration checks. Details of a particular calibration check can be displayed by highlighting the calibration check of interest by pressing the touch screen and then pressing SELECT. Press BACK to return to the **Main Menu** screen.

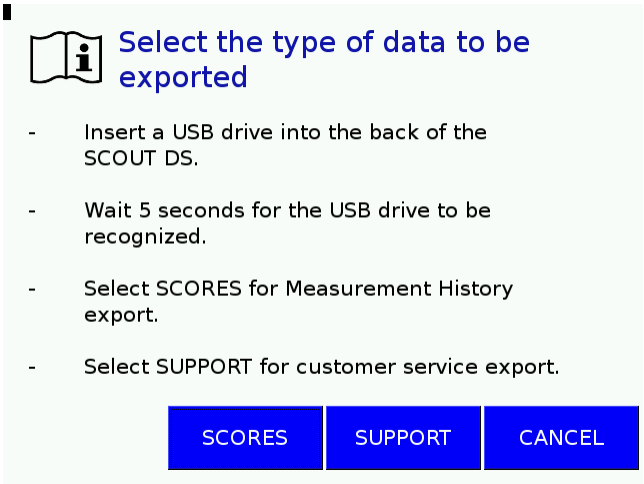
The **Event History** sub-menu (shown below) contains a history of the last 10,000 events recorded by your SCOUT DS device. Events can be due to either normal operation or errors.



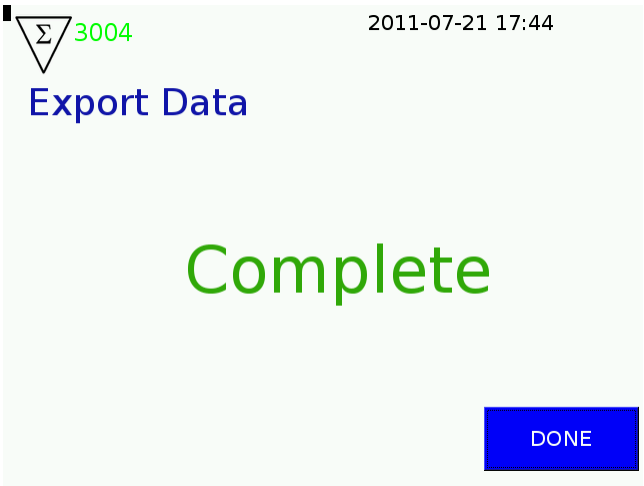
Press PG UP and PG DOWN to scroll through and view the events. Details of a particular event can be displayed by highlighting the event of interest by pressing the touch screen and then pressing SELECT. Press BACK to return to the **Main Menu** screen.

The **Mask Measurements** option will mask all patient measurements stored in the **Measurement History** up to the time the masking option is chosen. Subsequent measurements will not be masked until another **Mask Measurements** command is executed. **Once a measurement has been masked, it cannot be recovered.** This option is intended for movement of the machine between customers/sites, where measurements from the previous customer are considered sensitive and should not be viewed by subsequent customers.

The **Export Data** sub-menu allows the operator to export the SCOUT DS patient measurements and data useful for customer service to an external USB flash drive. Selecting the Export Data menu option brings up the following sub-menu:



Follow the instructions on the screen to export the patient **Measurement History** or support information. When the export is complete, the following screen will appear:

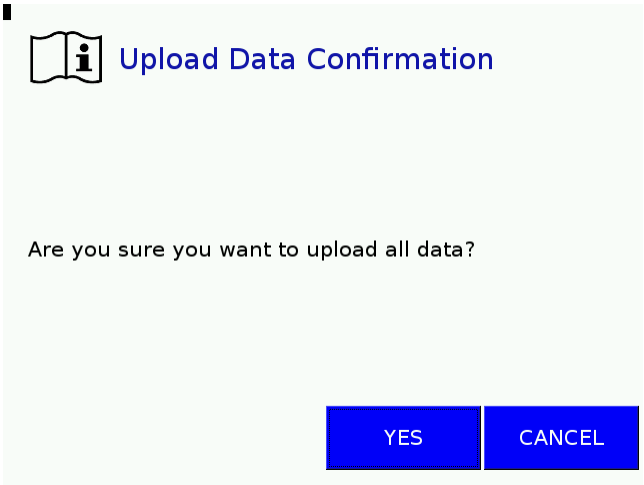


Press DONE to return to the **Data Management** sub-menu.

The **Upload Data** sub-menu allows the operator to upload clinical trial information via the internet to an external data server.

NOTE: This function is not normally used and is for clinical trials only.

If this option is chosen, the following sub-menu will appear:

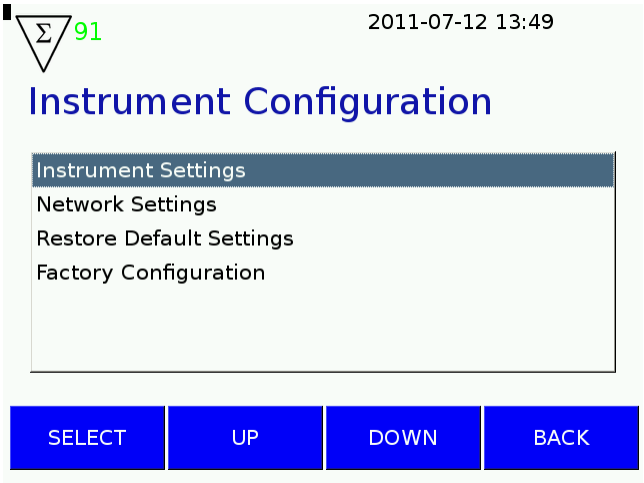


Press YES to upload all data files. The SCOUT DS will count as it uploads files and then indicate completion when done.

NOTE: Uploads will not occur if the SCOUT DS is not connected to the internet, the network settings are incorrect, or the local site's firewall is improperly configured. If this option is required, please contact your VeraLight Distributor or VeraLight technical support at 505-272-7023, or email customerservice@veralight.com for assistance.

d. Instrument Configuration

The Instrument Configuration sub-menu is shown below:

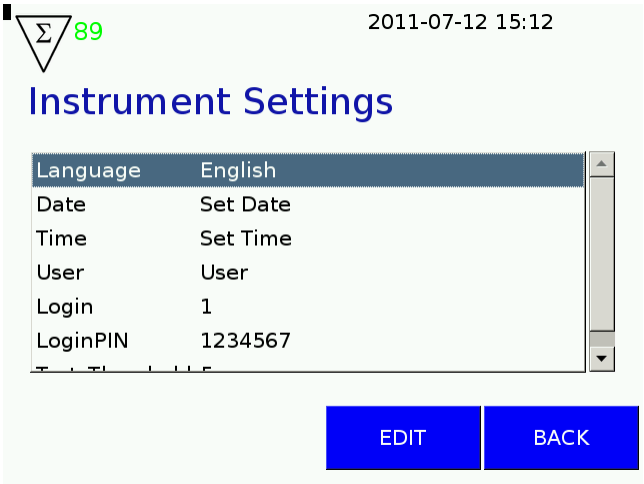


NOTE: The only sub-menus that should be used are **Instrument Settings** and **Restore Default Settings**.

NOTE: Network Settings or **Factory Configuration** are special settings intended for clinical trials. For further information, please contact your VeraLight Distributor or VeraLight technical support by phone at 505-272-7023, or email customerservice@veralight.com before using these sub-menus. Changing these settings will not affect the operation or performance of the SCOUT DS.

e. Setting Time, Date, Login PIN, and Low Tests Threshold

To set the SCOUT DS time, date, LOGIN PIN, and/or low tests threshold, select the **Instrument Settings** entry from the **Instrument Configuration** sub-menu**.** The **Instrument Settings** sub-menu is accessed by highlighting that entry and pressing the touch screen. Once highlighted, press SELECT to enter the sub-menu. The **Instrument Settings** sub-menu (shown below) allows the user to set the date, time, LOGIN PIN, and low tests threshold.



To change a setting, highlight the setting of interest by pressing the touch screen over the setting, then press EDIT. Each setting provides guidance on the entry format and acceptable ranges. Generally, the user will only change the Date and Time to conform to their local time zone. If desired, the Tests Threshold can be increased, so an earlier warning is given when the SCOUT DS is running low on tests.

The figure below is an example for setting the DATE:

Once editing is complete, press DONE to return to the **Instrument Settings** sub-menu. If you decide to abort editing, press CANCEL.

To exit the **Instrument Settings** sub-menu and return to the **Instrument Configuration sub-menu**, press BACK.

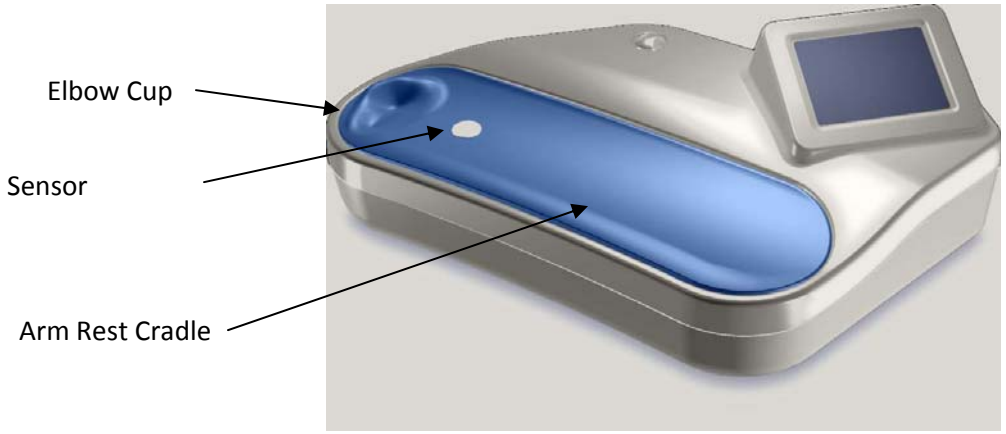
Selecting the **Restore Default Settings** restores the instrument settings to their factory defaults.

To return to the **Main Menu**, press BACK.

13. CLEANING AND MAINTENANCE

a. Cleaning the Sensor and Arm Rest

The Sensor must be cleaned after each measurement in order to assure optimal performance. The SCOUT DS will prompt the operator when cleaning is required (after each measurement). Always follow the cleaning procedure below, and use only VeraLight-approved/supplied cleaning products.



1. Use a new VeraLight-approved/supplied wet wipe to gently clean the Sensor with circular motions.

2. Immediately use a new VeraLight-approved dry wipe to gently dry and remove streaks from the Sensor.

3. After cleaning the Sensor, you can use the same wet wipe to periodically wipe the entire Arm Rest and Elbow Cup, taking care to avoid the Sensor so that residue is not transferred from the Arm Rest onto the Sensor.

b. Maintenance

The SCOUT DS does not require routine maintenance. Calibration checks with the Calibration Cap are performed automatically and periodically to ensure that the device is operating properly.

CARE OF THE CALIBRATION CAP

- **Caution:** It is very important to handle the Calibration Cap carefully and not to drop it, attempt to clean it, or mishandle it in any way. If the Calibration Cap is dropped or subject to any abuse, please notify VeraLight immediately.
- Proper care of the Calibration Cap includes keeping it over the Sensor when measurements are not being performed or keeping it on the Docking Station when measurements are being conducted.
- The Calibration Cap is affixed to the SCOUT DS device by a tether, which assures the correct rotational alignment of Calibration Cap on the Sensor.

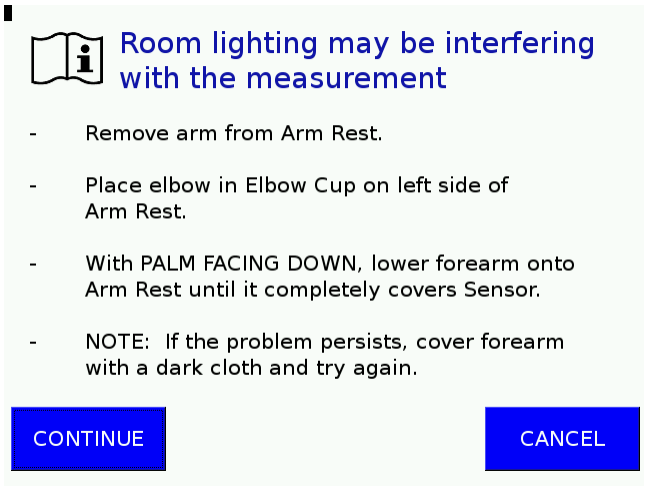
NOTE: Do not clean the Calibration Cap or expose the interior of the Calibration Cap to liquids or powders.

If contamination or damage of the Calibration Cap is suspected, please contact your VeraLight Distributor or VeraLight technical support immediately at 505-272-7023, or email customerservice@veralight.com.

14. TROUBLESHOOTING

a. Measurements

Forearm Position: During a measurement, the SCOUT DS may display the screen below if it is determined that the forearm insertion does not satisfy the quality control metrics for an accurate measurement.

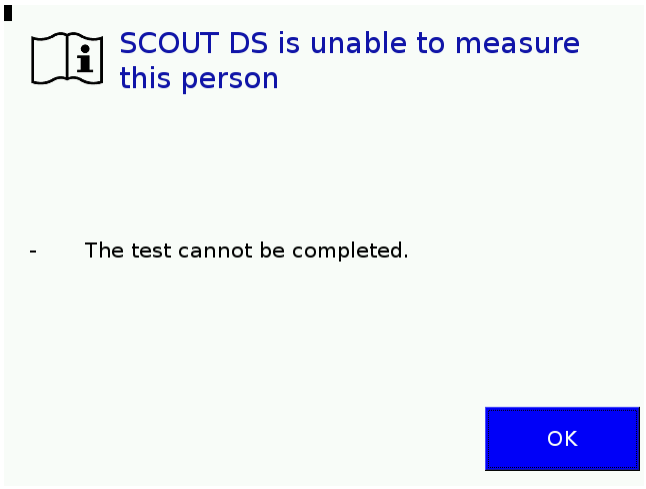


The following table lists common causes of forearm insertions not passing the quality control metrics and corresponding resolutions:

	Cause	Resolution
1	Calibration Cap left on Sensor during measurement	Remove the Calibration Cap from Sensor and place it in its Docking Station. Have the person insert his/her forearm, then press CONTINUE.
2	Person's forearm not covering or partially covering Sensor	Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.
3	Person moves forearm during measurement	Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.

4	Person has clothing over lower forearm during measurement	Have the person roll up his/her sleeve or remove his/her jacket, then reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.
5	Rooms lights detected during measurement	Certain persons have very thin and/or very dark forearms that may facilitate the lights penetrating the Sensor. Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, place a dark cloth over the forearm to block the room lights. Press CONTINUE.
6	Person has sunscreen or lotion on forearm	Ask the person if they have applied sunscreen or lotion to his/her forearm in the last 8 hours. If so, wash the forearm with mild soap and warm water, and then pat dry. Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.

Not Measurable Alert: After two valid insertions of the person's forearm, the SCOUT DS compares the first insertion to the second insertion for consistency. If the insertions are not consistent, the screen below will appear.

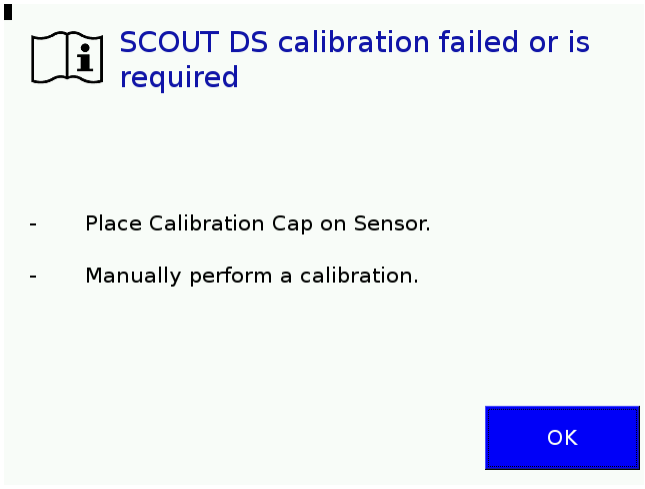


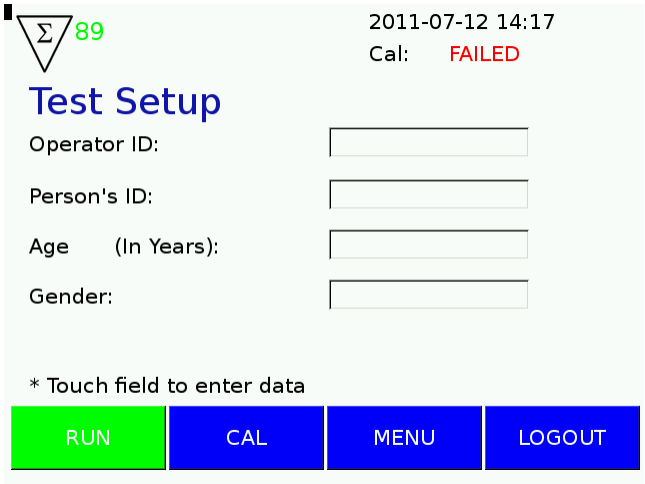
The following table lists common causes of a report of not measurable:

	Cause	Resolution
1	Person's forearm made poor contact with Sensor during 1st or 2nd insertion, or forearm not placed reproducibly in Arm Rest	Press OK to return to the **Test Setup** screen and retry the measurement, paying careful attention to how the person inserts his/her forearm. Make sure the person places his/her elbow in the Elbow Cup first and then carefully lowers their forearm, palm down, onto the arm rest, without rotation.
2	Mismatch in height of chair seat and SCOUT DS table top	Use a chair with a seat 46 cm (18") above the floor and place the SCOUT DS on a sturdy tabletop that is 61 cm (24") above the floor. Press OK to return to the **Test Setup** screen and retry the measurement. Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.
3	Person has sunscreen and/or lotion on his/her forearm	Ask the person if they have applied sunscreen or lotion to his/her forearm in the last 8 hours. If so, wash the forearm with mild soap and warm water, then pat dry. Press OK to return to the **Test Setup** screen and retry the measurement. Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.
4	Person has excessive hair on his/her forearm	Shave the forearm area that contacts the Sensor with shaving cream and a safety razor. Rinse with warm water and pat dry. Press OK to return to the **Test Setup** screen and retry the measurement. Have the person reinsert his/her forearm, being careful to place the elbow in the Elbow Cup and completely cover the Sensor with the forearm. Once the forearm is properly positioned, press CONTINUE.
5	Person has a tattoo, skin rash, cut, scar or other skin disruption(s) in the area contacting the Sensor	The person is not measurable by the SCOUT DS until the skin condition is cleared.
6	Person has extremely dark skin	The person is not measurable by the SCOUT DS because no light is detected.

b. Calibration Checks

The SCOUT DS may fail a calibration check if the Calibration Cap is not properly seated on the Sensor, the Sensor needs cleaning, a person's forearm is measured instead of the Calibration Cap, or if the device is too cold/hot. Resolving a calibration check failure must be done before measurements can be performed. Failure of the calibration check is indicated by the two figures below:





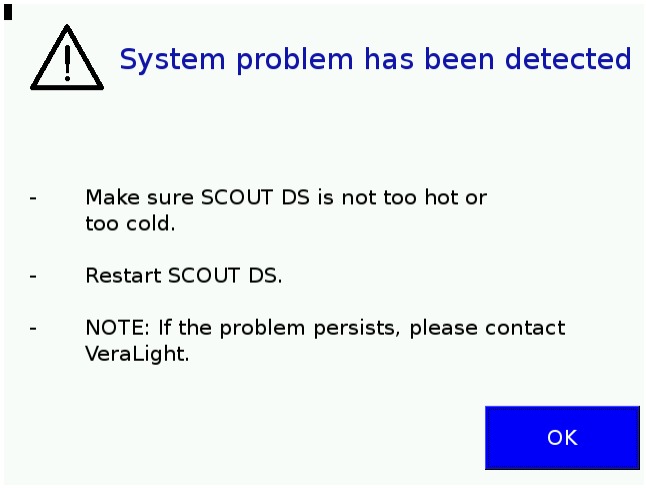
The following table lists common causes of calibration check failures and remedies:

	Cause	Resolution
1	Calibration Cap not on Sensor	Place Calibration Cap on Sensor, then manually run a calibration check by pressing CAL on **Test Setup** screen.
2	Calibration Cap not fully seated on Sensor	Make sure Calibration Cap is properly seated on Sensor, then manually run a calibration check by pressing CAL on **Test Setup** screen.
3	Forearm on Sensor during calibration check	Remove forearm from Sensor, clean Sensor with approved wipes, place Calibration Cap on Sensor, then manually run a calibration check by pressing CAL on **Test Setup** screen.
4	Sensor needs cleaning	Remove Calibration Cap from Sensor and place in Docking Station, clean Sensor with approved wipes, place Calibration Cap on Sensor, then manually run a calibration check by pressing CAL on **Test Setup** screen.
5	Calibration Cap removed from Sensor before calibration check complete	Place Calibration Cap back on Sensor, then manually run a calibration check by pressing CAL on **Test Setup** screen.
6	Instrument too cold or hot	Make sure ambient temperature in room is between 18^{o} C and 30^{o} C (64^{o} F to 86^{o} F), allow the SCOUT DS to equilibrate with room temperature for up to 60 minutes, then manually run a calibration check by pressing CAL on **Test Setup** screen.
7	Room lights too bright	Reduce brightness or move the SCOUT DS to another location that isn't as bright, then manually run a calibration check by pressing CAL on **Test Setup** screen.

NOTE: If the SCOUT DS calibration checks fail persistently after attempting the above remedies, please contact your VeraLight Distributor or VeraLight technical support at 505-272-7023, or email customerservice@veralight.com.

c. System Problems

The SCOUT DS may encounter hardware or software related system problems as illustrated in the figure below. To resolve a system problem, shutdown and power off the SCOUT DS. Wait 20 seconds and then power on the SCOUT DS. The SCOUT DS will attempt to go through its normal initialization sequence. If the system problem is resolved by the restart, you will be able to login and the calibration check status on the **Test Setup** screen should read PASSED. In this case, you may proceed with measurements.



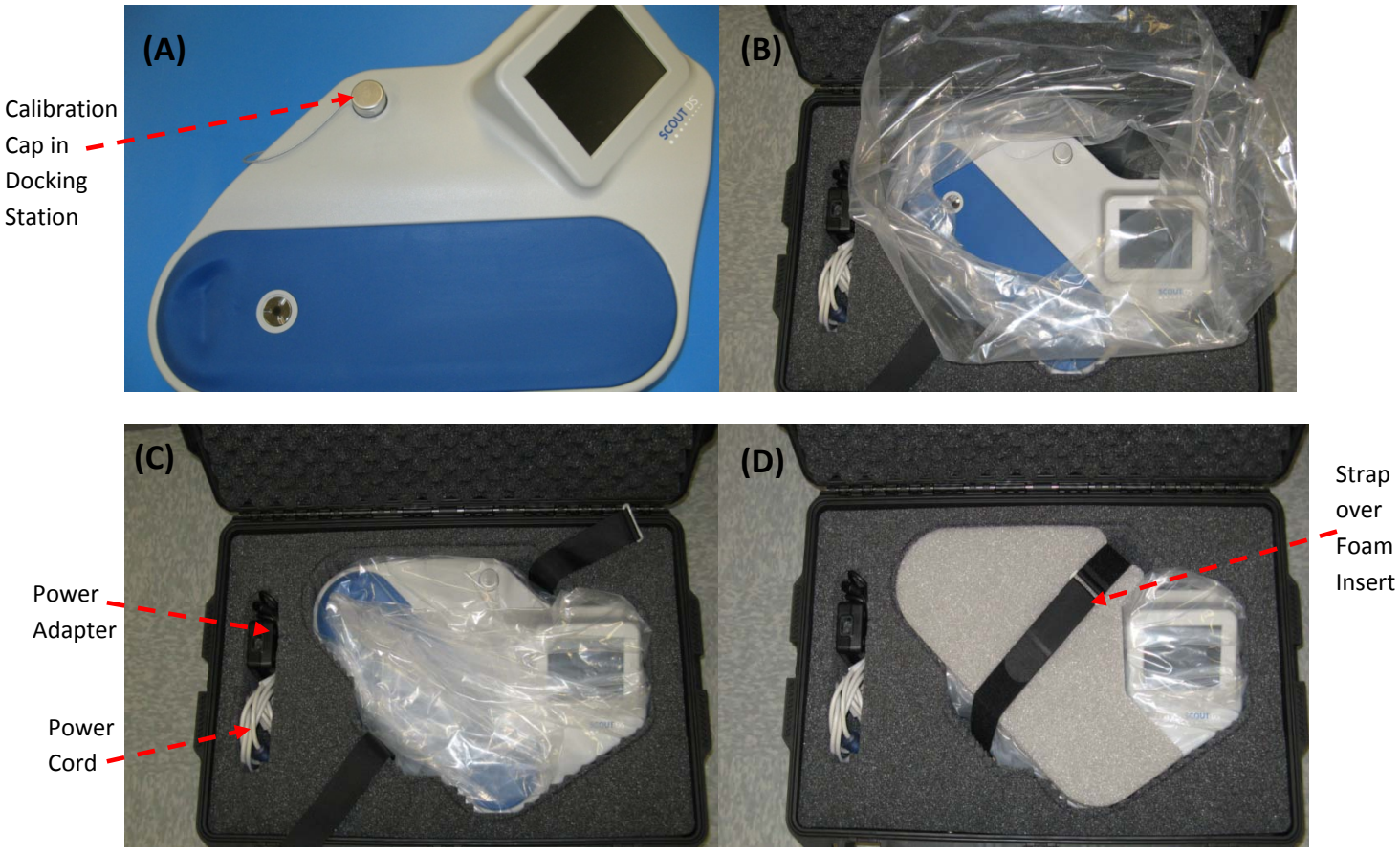
NOTE: If the SCOUT DS system problem persists after restarting the device, please contact your VeraLight Distributor or VeraLight technical support at 505-272-7023, or email customerservice@veralight.com.

15. TURNING OFF AND TRANSPORTING THE SCOUT DS® DEVICE

NOTE: Always use LOGOUT and SHUTDOWN (on Login Screen) when turning off the SCOUT DS device. Wait 20 seconds and switch the rocker switch on the backside of the SCOUT DS to the OFF position.

NOTE: Always transport the SCOUT DS in a plastic bag and in the protective shipping/carrying case. Do not leave the SCOUT DS in an uncontrolled environment such as a car, and do not allow the device to get wet.

A) Place the Calibration Cap in the Docking Station; **B)** Open the large plastic bag found inside the shipping case and gently place the SCOUT DS inside, always handling the SCOUT DS by its sides, not by the back of device; **C)** Place the Power Adaptor and Power Cord in the side compartment on the left and close the plastic bag around the SCOUT DS; and **D)** Place the custom foam insert on top of the device and then cinch the black strap over the foam to secure the SCOUT DS inside the shipping case.



16. WARRANTY, RETURN POLICY, AND COMPLAINT HANDLING

VeraLight, Inc. warrants the SCOUT DS to be free from defects in materials and workmanship for a period of one (1) year from the date of shipment to the customer. If the product fails to perform in accordance with product specifications, VeraLight, Inc. will repair or replace, at its option, the defective material or part. VeraLight, Inc. will pay customary freight charges for return of the defective SCOUT DS to the factory for repair and return back to the customer once repairs are complete. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to materials or workmanship. To exercise your rights under this warranty, contact your local, authorized VeraLight distributor, or VeraLight directly at 505-272-7023, or email customerservice@veralight.com.

In the event you have a complaint regarding product performance, patient safety, or effectiveness, please contact your VeraLight Distributor, or VeraLight at 505-272-7023, or email customerservice@veralight.com.

17. REFERENCES

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APPENDIX A EMC Information

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The SCOUT DS® is intended for use in the electromagnetic environment specified below. The customer or the user of the SCOUT DS® should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The SCOUT DS® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage Fluctuations/ Flicker emissions	Complies	
The SCOUT DS® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The SCOUT DS® is intended for use in the electromagnetic environment specified below. The customer or the user of the SCOUT DS® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SCOUT DS® requires continued operation during power mains interruptions, it is recommended that the SCOUT DS® be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The SCOUT DS® is intended for use in the electromagnetic environment specified below. The customer or the user of the SCOUT DS® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SCOUT DS® is used exceeds the applicable RF compliance level above, the SCOUT DS® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SCOUT DS®.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the SCOUT DS®			
The SCOUT DS® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SCOUT DS® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SCOUT DS® as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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