CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-6
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	8-11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7-9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11-13
	13b	For each group, losses and exclusions after randomisation, together with reasons	11-12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9-10
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16-18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	21
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-22
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

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

Scripps Wired for Health Study

Research Protocol

Protocol Version:	6.0
Version Date:	28April2014
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1.0 BACKGROUND

Chronic diseases such as hypertension, diabetes mellitus, and cardiac arrhythmias, continue to represent a significant healthcare burden on both patients and the healthcare system as a whole. The high prevalence of these conditions combined with well characterized complications that result in significant, negative impacts to quality of life has led to the appropriation of significant scientific and engineering resources to find ways to improve diagnosis and treatment that include advances in diagnostic technology and pharmaceuticals (ALLHAT, Ernst 2003, Uzu 2005).

Despite these efforts, the management of these conditions remains challenging (Hansen 2005). Patient engagement and adherence to outpatient medications and treatment strategies is poor (Guyatt 1986, Hansen 2005). Furthermore, patients' understanding of their disease condition, communication between them and appropriate health care providers, and their ability to identify early warning signs prior to clinical decompensation events is questionable. From the clinician perspective, appropriate tools that can provide the insight necessary to help manage chronic disease in the outpatient setting are lacking. These challenges have resulted in clinical and economic consequences such as disease progression in patients with poor control of chronic conditions, high utilization of emergency departments, inpatient resources, and readmissions to medical centers (Sander 2005).

Two related technology areas, wireless medicine and telehealth, may provide the tools necessary to improve care and reduce healthcare costs for a variety of common conditions. Using mobile computing platforms such as smartphones, internet connectivity, and novel biomedical sensors, wireless medical devices can measure disease metrics that can be analyzed for patterns and be used by both patients and providers to make proactive healthcare decisions. Previous work using wireless health telemedicine technology has shown significant improvements in disease management for hypertension (HTN), diabetes mellitus (DM), arrhythmias (Budinger 2003, Clifford et al. 2012, Darkins et al. 2008, Rothman 2007). Other research using a tool to enable remote assessment of patients with a several chronic conditions helped to identify those patients that needed direct clinician intervention, but in a proactive manner.

The latest generation of wireless health devices sport improvements in accuracy, usability, and compatibility with ubiquitous smartphones and clinical software. Additionally, the availability of smartphones, the evolution of algorithms used to analyze health data, and techniques for data visualization may improve patient and clinician interpretation of health data, disease management, and outpatient detection of physiologic states such as clinically significant arrhythmia. Given the base of evidence for telemedicine for outpatient disease management and the features of the latest wireless health technology it would be useful to evaluate the feasibility of using a suite of smartphone compatible wireless health devices on patients with hypertension, diabetes mellitus, and cardiac arrhythmias.

2.0 STUDY DESIGN

2.1 Purpose

We propose to evaluate the impact of using a smartphone enabled "Wireless Monitoring System" in conjunction with a disease management program on the healthcare costs and resource utilization of chronically ill individuals with diabetes, hypertension, and cardiac arrhythmia.

The intervention consists of:

- Wireless medical devices (glucometer, blood pressure monitor, and/or mobile ECG)
- Healthy Circles online patient portal and connected care coordination platform (branded for the study as the "Health Comp" online portal)
- Disease management program managed by Health Comp.

We aim to specifically target our wireless monitoring intervention to be used by chronic disease "hot spotters;" the small number of patients identified, through medical billing data, to account for the highest healthcare spending and resource utilization.

We predict that the benefits to patients from using wireless monitoring will be increased understanding of their disease, increased health self-management (e.g., self-efficacy), more transparency regarding their chronic conditions, and improved care coordination by staff members in the wellness program. Ultimately, we further hypothesize that this may result in improved therapeutic adherence, proactive medical choices, and better management of their chronic conditions as measured by disease specific physiologic markers. We hypothesize that these benefits directly translate to decreased acute care visits, decreased inpatient health service utilization (hospital admissions, days of hospitalization) and decreased outpatient health service utilization (emergency department visits, need-based primary care clinic visits, and need-based specialty clinic visits) and will ultimately lead to significant reductions in health care costs for the treatment group relative to a control group and relative to pre-monitoring utilization rates. Study participants will be currently enrolled in or willing to be enrolled in Health Comp's Disease Management program.

This study is a collaboration between Scripps Translational Science Institute, Scripps Wellness, Qualcomm Life, Health Comp (the third party administrator for Scripps Health responsible for processing all health care insurance claims for employees and dependents) and Healthy Circles. This study is designed as a pilot study to determine the feasibility of deploying this type of intervention with multiple chronic disease groups, and to inform the design of a larger trial to further assess the impact and effectiveness of wireless monitoring interventions.

2.2 Preliminary Data

The principles of biomonitoring including a survey of device technologies, methods, and barriers have been studied (Budinger 2003, Clifford et al. 2012). The benefits of decreased health service utilization in particular through wireless monitoring have been shown by the Veterans Administration (VA) with a 0.7% decrease in health utilization over a cohort of 1963 patients (Darkins et al. 2008). Cell phones, in particular, have been extensively studied in their role as facilitators of telehealth; a systematic review of 25 studies encompassing 38,060 patients that used cell phones for outpatient health monitoring for a variety of conditions showed improvements in hemoglobin A1c in diabetics, improved control of asthma symptoms, better medication adherence, and process improvements (Krishna et al. 2009).

Furthermore, individual studies and meta-analyses focused on telehealth monitoring of diabetes, hypertension, and arrhythmia have also shown significant promise. A large meta-analysis of 21 studies using cell phones for the management of diabetes, 8 of which were powered to measure significant DM outcomes, showed significant promise in terms of improved glycemic control, self-efficacy, and hemoglobin A1c (Holtz et al. 2012). Furthermore, ambulatory electrocardiographic monitoring has also demonstrated the ability to detect clinically significant arrhythmias in the outpatient setting (Rothman et al. 2007). Finally, sustained improvements in the control of hypertension using home monitoring and management of blood pressure have been demonstrated in a number of previous trials (McManus et al. 2010, Wakefield et al. 2011).

We have evaluated available demographic and billing pattern data from Health Comp pertaining to our target populations for this trial. From a denominator of 28,425 active members, there were 21,691 individuals who had at least one claim in 2012. From this number, there were 4,060 individuals who billed for CPT codes related to hypertension, diabetes, and/or arrhythmias. After excluding individuals under the age of 18 years, a total of 3,999 individuals remained, and we have shown a breakdown of demographic and billing metrics for individuals in each of our target condition categories in the table below. These data suggest the utility of this data source for identifying our "hotspotter" target disease populations and the sampling frame from which we will recruit the participants who will comprise our study sample.

Table 1.

Total N = 3999	Hypertension	Diabetes	Arrhythmia	Co-morbid (2 or more)
N (% of Total) §	3222 (80.6%)	1304 (32.6%)	651 (16.3%)	1087 (27.2%)
Age (Mean Years)	54.4 (10.9)	53.7 (11.4)	52.4 (14.1)	56.5 (10.2)
Office Visits (Mean #, SD/Median)	6.8 (6.1)/5	7.2 (6.6)/6	9.1 (7.9)/7	8.2 (7.1)/6
Condition Specific Costs (Mean $, SD/Median)	2,894 (10,310)/312	3,628 (12,269)/521	5,189 (23,445)/179	N/A
Total Costs (Mean $, SD/Median)	10,699 (30,095)/2,265	10,532 (31,954)/2,206	24,901 (52,058)/6,301	16,364 (41,944/3,133

2.3 Experimental Flow

This study will utilize a randomized controlled design. Health Comp will identify Scripps plan members with a history of diagnostic billing codes consistent with either diabetes (insulin dependent diabetes and non-insulin dependent diabetes), hypertension or cardiac arrhythmia. They will be recruited from a list of individuals associated with the highest utilization rates and costs over the past two 6-month periods. A sufficient number of participants – we estimate approximately 1,000 - will be contacted to yield a total of 200 study subjects. Of the individuals in this group, 100 will be randomized to receive the wireless monitoring intervention (Monitoring Group) plus Health Comp Disease Management program and 100 will be randomized to receive the standard Health Comp Disease Management program only (Control Group).

The participants randomized to the Monitoring Group will be provided with an iPhone 4 or 4s, access to the Healthy Circles portal and program, and the wireless device(s) that are appropriate for monitoring their particular medical diagnoses. Patients will use the wireless monitoring system for a period of six months. As was done for the two 6-month periods prior to the intervention, health service utilization rates will be obtained for the six months during the wireless monitoring intervention period.

All patients will also be enrolled in the Health Comp disease management program which involves outreach by Health Comp nursing staff for the purposes of relaying medical education and wellness information with regard to disease prevention and chronic disease management.

Upon completion of the study, participants in both groups will receive a $20 gift card, in addition to 32 Scripps Health Wellness points for participation in the study. If an employee earns 100 Wellness points in a calendar year (through participating in other Scripps Wellness activities), they are eligible for a reduction in health insurance costs.

These wellness points will be earned in the following categories:

- 10 credits for Health Coaching (there is a 10 credit maximum per year)
- 4 credits for Completion of the Baseline Survey and Follow Up Survey (there is a 4 credit maximum for survey completion each year)
- 18 credits for Personal Health Activities (there is a 36 credit maximum per year)

Wellness points for the study will be awarded at the end of the fiscal year – September 2014.

A diagram of the study design can be found in Appendix 1.

2.4 Methods

Recruitment and Consent:

In order to provide awareness of the study, an e-mail was sent from Human Resources to all Scripps Health employees (Appendix 20).

Health Comp and Scripps Health have established a protocol for Health Comp to contact members (Scripps employees and their dependents) to discuss their medical conditions and health status. To identify these members, Health Comp conducts regular queries of their medical billing database to identify those members who have medical claims consistent with chronic disease.

For the purposes of this study, members who are identified as having one or more of the targeted chronic diseases (diabetes, hypertension or cardiac arrhythmia) with high medical resource utilization will be sent a letter (Appendix 2) introducing Health Comp and informing the member that they will be contacted by Health Comp staff to discuss their health and medications. Within 2 to 4 weeks, a Health Comp staff member (typically a RN or LVN) will follow up with a telephone call to the identified patients (Appendix 3). Patients will also be given the option of contacting Health Comp. The staff member will discuss the patient's medical status and introduce the Disease Management program. A description of the standard Disease Management Program already in use by Health Comp is included in Appendix 4. The member then has the option of joining the program or opting out of any further calls or contact.

If a patient joins the Disease Management program and they meet the inclusion/exclusion criteria of the study, the nurse will also present the opportunity for them to participate in the trial. The study will be thoroughly discussed, including participants' responsibilities and rights, risks and benefits, and method for withdrawing.

The nurse will explain that upon completion of the call, the patient will receive a link to the Informed Consent form via e-mail or 2 paper consent forms along with a letter of explanation will be sent by mail. They will be asked to carefully read the document and will be given a phone number to call if they have any additional questions regarding the study. Patients who read the consent and have no additional questions will be asked to electronically sign the consent form or sign the paper copy. They will keep one for their records and mail the other to HealthComp in a self-addressed stamped envelope (provided). If, after 10 business days, HealthComp has not received the returned consent, a staff member will reach out to the participant. After completing the informed consent, they will be directed to an on-line baseline survey (Appendix 5). For participants completing the paper consent, a link to the baseline survey will be sent to the member via email. HealthComp will send a copy of the consent form to the Study Coordinator. Surveys will also be completed 6 months, and the survey will be similar to the Baseline survey (Appendix 21). If a patient expresses an interest in participating in the study but does not register online and complete the consent form, four attempts to re-engage the patient will be made via phone call and/or email. If after four attempts no confirmation of participation has been established with the patient, this will be considered a "screen failure." Any patient who elects not to participate in the study will still be offered participation in the Disease Management program outside the auspices of the study.

After study staff have received notification that the patient has signed the Informed Consent form and completed the baseline survey, a staff member will call the patient again and schedule the Enrollment visit. This visit will be conducted by a Scripps Research Coordinator or Research Assistant at a Scripps facility convenient to the patient. It will be explained to the patient that Scripps Health (employer) will not have access to their medical or clinical information that is used for the study. The data collected for the study, including survey data, usage data from the online data platform, and biometric information collected from the wireless devices, will be used for study purposes only. He/she will also understand that if they choose not to participate, this visit will be cancelled and there will be no further contact regarding the study. (The patient may still elect to participate in the Disease Management program which includes communication with Health Comp staff but without the wireless monitoring system provided by the study.)

Randomization

Patients will be randomized to one of two study groups (Monitoring group or Control group) after they sign the consent form and complete the baseline survey, They will be notified of their group assignment at the Enrollment visit.

Health Data and Assessments:

The data for this study will be collected via online web-based surveys, electronic medical records, Healthy Circles web portal and Health Comp billing data. Biometric data, including blood pressure and blood glucose will be collected at both Enrollment and Termination visits with study staff.

The Study Coordinator/Assistant (Scripps employees) will review the patient's medical records and verify hospital admissions, days of hospitalization, emergency department visits, need-based primary care clinic visits, need-based specialty clinic visits lab results and procedures. Biometric readings of blood pressure, blood glucose, HgA1c, and ECG readings will also be recorded and used for data analysis. Only data related to the study's endpoints will be recorded and utilized.

The online Survey platform "Survey Monkey" and the Healthy Circles software platform will be utilized. Surveys will be administered at Baseline, and at completion of monitoring (6-months from start). An email will be sent to the participants half way through the study to extend them an opportunity to give feedback.

The survey will include measurement of: Demographics, Health History, and Health Literacy; (b) Health Care Resource Consumption (self-reported) and Health Self-Management (Health Locus of Control, Health Self-Efficacy, and Patient Activation); (c) Health-related Quality of Life, Physician-Patient Communication, and Medication Adherence; and (d) Physical Activity/Exercise and Attitudes towards technology (Innovativeness and Personal Involvement). In the Monitoring Group only, the survey will additionally include measures of (e) Device/system Usability, Satisfaction with Device (CSI 6-items), Utility of Monitoring, and Motivation for Tracking/compliance.

Schedule of Events: The schedule of events for the study is as follows:

ALL POTENTIAL PARTICIPANTS

Initial Outreach Letter (Health Comp)

- Introduce partnership of Scripps and Health Comp
- Invite to join Disease Management program.
- Present study and review risks, benefits and responsibilities.
- List options for contacting Health Comp, if interested in study.

Screening Telephone Call (Health Comp)

- Discuss Disease Management program.
- Present study and review risks, benefits and responsibilities.
- Complete screening form, with eligibility criteria, if patient interested in study

Patient On-line Activity (Patient, Health Comp as needed)

- Review Informed Consent form and call Health Comp nurse with any additional questions about study.
- Sign Informed Consent form.
- Complete Baseline Survey.

Post-Consent Telephone Call (Scripps Study Coordinator)

- Schedule enrollment visit.
- Patient randomized to Monitoring Group or Control.

PARTICIPANTS RANDOMIZED TO MONITORING GROUP

Enrollment Visit (Scripps Study Coordinator): Patients will come to one of the Scripps Enrollment Visit sites 1-4 weeks after consent obtained.

- Review study requirements.
- Sign Terms of Use agreements for Healthy Circles portal, iPhone, iTunes and device(s).
- Complete Baseline Survey if not already completed.
- Enroll patient in Healthy Circles.
- Train patient on use of iPhone and/or app(s).
- Train patient on use of device.
- Record baseline readings for device that patient will use during study (blood pressure, ECG, or blood glucose) (for Diabetics also obtain HgA1c)

Telephone Call to Patient (7-10 days after Enrollment Visit) (Health Comp)

- Confirm connectivity and answer questions about operation of devices.
- Introduce the Health Comp Disease Management Program (distinct from Healthy Circles but with overlap in the educational materials used)
- Confirm study participation

Telephone Calls to Patient (at any time during the study) (Health Comp)

- According to current Health Comp protocol, this occurs when patients are non-compliant with picking up prescriptions from the pharmacy or getting recommended lab tests.

Healthy Circle Messages to Patient (at any time during the study) (sent electronically)

- According to a pre-determined protocol (see section below on Monitoring and Log-on Schedule) patients will receive messages on their i-Phone or computer via the Healthy Circles platform if they fail to take the prescribed number of weekly readings for their particular device(s).

3-month E-mail to Patient (Scripps Study Coordinator)

- Extend the participant an opportunity to provide feedback on their experience as a study participant.

6-month Follow-up Telephone Call to Patient (Health Comp)

- Schedule final termination visit.
- Set expectation that they will get link via email to do final survey.
- Discuss continuation in Disease Management Program (distinct from Healthy Circles).

6-month E-mail to Patient (Health Comp)

- Remind participant to complete on-line 6-month survey.

Final Study visit (Scripps Coordinator)

- Return study devices
- Record final readings for devices that patient used during study (for Diabetics also obtain HgA1c).
- Have participant to complete 6-month survey during the visit, if not already completed
- Inform patient that32 Wellness points will be awarded in September 2014 and award a gift card ($20)

PATIENTS RANDOMIZED TO CONTROL GROUP

Enrollment Visit (Scripps Study Coordinator): Patients will come to one of the Scripps Enrollment Visit sites 1-4 weeks after consent obtained to:

- Review study requirements.
- Complete Baseline Survey if not already completed
- Record baseline readings of the measurements appropriate for patient (blood pressure, ECG, or blood glucose) (for Diabetics also obtain HgA1c).

Telephone Call to Patient (7-10 days after enrollment visit) (Health Comp)

- Introduce the Health Comp Disease Management Program.
- Confirm study participation

Telephone Calls to Patient (at any time during the study) (Health Comp)

- According to current Health Comp protocol, this occurs when patients are non-compliant with picking up prescriptions from the pharmacy or getting recommended lab tests.

3-month E-mail to Patient (Scripps Study Coordinator)

- Extend the participant an opportunity to provide feedback on their experience as a study participant.

6-month Follow-up Telephone Call to Patient (Health Comp)

- Schedule final termination visit.
- Set expectation that they will get link via email to do final survey.
- Discuss continuation in Disease Management Program.

6-month E-mail to Patient (Health Comp)

- Remind participant to complete on-line 6-month survey.

Final Study visit (Scripps Coordinator)

- Record measurements appropriate for patient (blood pressure, ECG and/or blood glucose) (for Diabetics also obtain HgA1c).
- Have participant to complete 6-month survey during the visit, if not already completed. Inform patient that 32 Wellness points will be awarded in September 2014 and award a gift card ($20)

Healthy Circles On-line Platform:

Healthy Circles is an iPhone connected care coordination platform, which includes an integrated suite of online Care Management and Consumer Portals that can deliver chronic disease educational information and link patients to their families, caregivers, and healthcare professionals. Through a collaboration with Qualcomm Life's 2net platform, Healthy Circles also now includes a dashboard that displays the patient's device monitoring results and trends over time. (For the purposes of this study, the website will be branded with the Health Comp logo.) Data from the device(s) will be wirelessly uploaded to the patient's Healthy Circles account and accessible via the patient's i-phone or computer. Also included in the platform will be resources which provide information about the patient's disease condition and standard general health behavior recommendations.

iPhone and Wireless Devices

All patients in the monitoring group will be provided with an iPhone 4 for the purposes of the study. Participants will return the study iPhone and devices at the end of the study.

Portal and Device Training and Patient Support:

As shown, patients randomized to the monitoring group will be trained on how to use their study iPhone, the HealthyCircles portal, and their device(s) at their Enrollment Visit. Patients will also be provided with a contact email and phone number they can use to reach a study staff member for first tier technical and other study support.

The devices for the study include:

1. iBGStar - iPhone enabled capillary blood glucose meter. The iBGStar is an iPhone hardware extension that functions as a conventional, outpatient glucometer using specialized test strips and lancets, which will be provided to the participant, to measure blood glucose from a patient's peripheral blood using a finger stick. Accuracy, speed, and method of operation are comparable to current outpatient glucometers. The device is designed to seamlessly integrate with an iPhone to visualize and store blood glucose readings. However, the device does not require an iPhone for operation and can be used as a stand-alone glucometer. The device has FDA 510(k) clearance.

2. Withings Blood Pressure Monitor - iPhone enabled blood pressure monitor. This automated blood pressure cuff uses an internal battery source, separate from an iPhone, to initiate an oscillometric measurement of systolic and diastolic blood pressure. Again, accuracy and speed of measurement is comparable to other automated outpatient blood pressure cuffs. The method of operation includes connecting the cuff to an iPhone and initiating the measurement through the iPhone user interface. A software algorithm controls inflation and deflation of the cuff as well as determination of blood pressure which is displayed on the iPhone screen. The device has 510(k) clearance by the FDA.

3. AliveCor - iPhone enabled ECG monitor. This device uses the iPhone for data processing, visualization, and recording of a single lead ECG signal when its two sensors are held against the chest by the patient or between the fingertips. The ECG signal captured by the device can be recorded and reviewed post measurement. Specifically, AliveCor will provide an interpretation of every reading taken by the patient through AliveCor's partnership with e-cardio, within 30 minutes from when the measurement was taken. That interpretation will then be viewable by the patient in his or her HealthyCircles portal. A Health Comp Nurse will review the Healthy Circles portal each business day to see if an ecardio report has surfaced, if so, the nurse will call the patient within the next business day. AliveCor received FDA 510(k) clearance in December 2012.

See Appendices for of Use Agreements, End User License Agreements and Device agreements

Monitoring and Log-on Schedule

Patients will be requested to monitor their health condition at regular intervals as summarized in Table 2 below. If their monitoring falls below the level defined in the "Poor Compliance" range, they will receive an e-mail on the Healthy Circles platform and their personal e-mail and/or a text message on their study phone reminding them of the monitoring schedule. After a pre-defined time period of no readings, the patient will receive a call from a Health Comp nurse.

Call from Health Comp Nurse

The purpose of this call will be to discuss the patient's participation in the study. If the patient is interested in continuing and has had difficulties with their device(s) or the program, the nurse will talk to the patient about reasons for non-participation and will brainstorm strategies for overcoming schedule issues, device problems, logging on to the portal, etc. If the patient indicates that s/he wants to stop study, the Health Comp nurse will notify the Scripps study coordinator and s/he will call the patient to set up a time to return the devices.

Table 2: Device Monitoring Schedule (HTN=Hypertension group, NIDDM=Non-insulin dependent Diabetes Group, and IDDM=Insulin-dependent diabetes group)

Device	Study Frequency	Poor Compliance	Patient Initiated Monitoring
HTN: Withings	2 x per day, 3 days per	< 3 x per week for 2	Symptoms including but not limited to

BP	week, 1st one in a.m.	consecutive weeks	visual disturbance, "bounding" pulse, chest discomfort, nausea
NIDDM: iBG Star	1 x per day (pre-meal), 3 x per week	< 3 x per week in 1 week	Symptoms including but not limited to fatigue, visual changes, pre-syncopal symptoms, dyspnea, nausea, vomiting
IDDM: iBG Star	4 x per day (pre-meal, with 4th reading at bedtime, 2 hours after last meal/dinner), every day	< 4 x per day for 3 days in 1 week	Symptoms including but not limited to fatigue, visual disturbance, pre-syncopal symptoms, dyspnea, nausea, vomiting
Arrhythmia: Alive Cor ECG	if symptomatic	< 1 reading in 2 weeks will trigger message to confirm lack of symptoms, for 30 seconds	Symptoms including but not limited to chest discomfort, palpitations, rapid heart rate, feeling of "skipped beats," dyspnea, nausea, pre-syncopal symptoms

Hypertension

All patients in the hypertension intervention group will be asked to take their blood pressure at least 3 times per week during the study. If a patient reaches the non-compliance level as outlined in Table 2, they will receive the following message on their message board:

> For the purposes of the study, please take your blood pressure a minimum of 2 times per day, 3 days per week with the first measurement in the morning. In addition, you should also take your blood pressure if you experience visual changes, "bounding pulse", chest discomfort or nausea. Thank you for your continued participation.

If a patient has an additional instance of non-compliance (<3 readings per week for 2 consecutive weeks), the Health Comp nurse will call them and discuss their participation and brainstorm solutions to problems that might be preventing the patient from taking their blood pressure. .

Measurements that meet the following criteria will trigger a message from the Health Comp nurse that contains hypertension educational content related to medication compliance, diet, exercise etc.
>140/90mmHg on 2 measures in 1 week for 2 consecutive weeks

> We have noticed that lately you have had 2 or more blood pressure readings that are considered elevated. Please check out the documents in the Resources tab for ways to reduce your blood pressure and improve your heart health.

Non-insulin Dependent Diabetes Mellitus

All patients in the non-insulin dependent diabetes intervention group will be asked to measure their blood sugar according the frequency in Table 2. If a patient reaches the non-compliance level as outlined in Table 2, they will receive the following message on their message board:

> For the purposes of the study, please check your blood sugar a minimum of 1 time per day (pre-meal), 3 days per week. In addition, you should also check your blood sugar if you experience fatigue, visual changes, dizziness, light headededness, shortness of breath, nausea or vomiting. Thank you for your continued participation.

If a patient has an additional instance of non-compliance (< 3 reading per week for 1 week), the Health Comp nurse will call them and discuss their participation and brainstorm solutions to problems that might be preventing the patient from taking their blood glucose.

Over a 48 or 72 hour time period, measurements that meet either of the following criteria will trigger a message from the Health Comp nurse.

- Any 2 or more readings >250mg/dl over a consecutive 48 hour period.
- Any 2 or more readings <65mg/dl over a consecutive 72 hour period.

> We have noticed that lately you have had 2 or more blood glucose readings that are considered elevated. Please check out the documents in the Resrouces tab for ways to reduce your blood glucose and improve your health.

Insulin Dependent Diabetes Mellitus Group

All patients in the insulin dependent diabetes intervention group will be asked to measure their blood sugar according the frequency in Table 2. If a patient reaches the non-compliance level as outlined in Table 2, they will receive the following message on their message board:

> For the purposes of the study, please check your blood sugar at minimum before every meal and again at bedtime. In addition, you should also check your blood sugar if you experience fatigue, visual changes, dizziness, light headedness, shortness of breath, nausea or vomiting. Thank you for your continued participation.

If a patient has an additional instance of non-compliance (< 4 readings per day in 1 week), the Health Comp nurse will call them and discuss their participation and brainstorm solutions to problems that might be preventing the patient from taking their glucose reading.

Over a 48 or 72 hour time period, measurements that meet either of the following criteria will trigger a message from the Health Comp nurse.

- Any 2 or more readings > 250mg/dl over a consecutive 48 hour period.
- Any 2 or more readings <65mg/dl over a consecutive 72 hour period.

> We have noticed that lately you have had 2 or more blood glucose readings that are considered elevated. Please check out the documents in the Resources tab for ways to reduce your blood glucose and improve your health.

Arrhythmia

All patients in the arrhythmia intervention group will be asked to take an ECG only when symptomatic. If a patient does not record an ECG in 2 weeks, the following message will be sent to the patient's message board on the Health Comp portal.

> Thank you for your participation in the Wired for Health study. We have asked you to take an ECG if you have any symptoms (chest discomfort, palpitations, rapid heart rate, feeling of "skipped beats," light headedness, "bounding pulse", shortness of breath, visual changes or nausea). Since we haven't heard from you, we're assuming that you remain symptom free. Will you please confirm this by sending us a return message? Click on "Reply All" in the lower right hand corner of the message and just let us know you haven't had any symptoms that needed monitoring. Thank you very much.

If a patient does not reply to the message 3 times (6 weeks of no readings or replies), the Health Comp nurse will call them and discuss their participation and educate them about the process of responding to an e-mail.

When a patient has symptoms and s/he takes a reading with the AliceCor ECG, they will be asked to take it for a full 30 seconds. The ECG is uploaded to eCardio, a cardiac monitoring service and read by a physician. At the enrollment visit the patient will be instructed to log-in to their Health Comp portal approximately 30 minutes after taking a reading, to view the report. (See Appendix 19 for a sample report.)

The report will summarize the measurements recorded on the ECG. The patient will be instructed to note the analysis of the current event as either "Stable," "Serious," or "Critical." They will have received previous instructions and documentation with the following recommendations:

- Stable: This rhythm is stable. However, if you feel unwell in any way or have any symptoms of concern please contact a medical provider.
- Serious: This is a serious rhythm. Consultation with a medical provider is advised.
- Critical: Immediate medical consultation is advised.

Within 72 hours, the Health Comp nurse will call the patient to insure they received the report, have read it and understand it. Once a patient has demonstrated that they are logging on and reviewing the report, the Health Comp nurse will no longer call them.

Patients will be reminded at the enrollment visit that their measurements are not being viewed in real time, so should they experience symptoms that they feel require medical attention, they should call 911 or go to the emergency room. The readings conducted for the study do not replace the acute medical attention that a patient may need at the onset of symptoms.

Data Aggregation and Access:

Via connection with Qualcomm's 2net platform, Healthy Circles will aggregate all readings from the wireless devices. The 2net platform, a wireless hardware hub, supplied by Qualcomm, will act as the home gateway from the iPhone to the Healthy Circles portals. Data security for the phone will consist of password protection for general iPhone access as well as an additional layer of security consisting of a login, to access the HealthyCircles portal. These measures, in addition to the data encryption methods employed by the devices and software platforms are HIPAA secure. Similarly, a log-in will be required to access the HealthyCircles portal through conventional computer Internet access. For the selected wireless devices, data will be transmitted through the iPhone's cellular network, aggregated at the 2net platform, and sent as a consolidated secure stream to the Health Comp branded HealthyCircles platform. Transport methods supported by each sensor provider will be leveraged in order to collect data securely from the iPhone, and aggregate at the 2net platform.

As is currently the case as part of the Disease Management program, Health Comp will review data for patients in both groups for noncompliance with prescription refills, preventive screenings, etc. They will either send a "deficit letter" or call the patient (according to their current protocol) to alert him/her of the finding.

Follow-up Surveys

Patients will receive e-mails to complete the 6 month survey 7 days before the anticipated due date. If they haven't completed the survey 7 days after the due date, a reminder e-mail will be sent. An additional reminder will be sent on day 14. On day 21, the Health Comp nurse will make a call to remind the patient, and if necessary, assist the patient with logging into the survey and completing it. If the patient is unable to complete the survey at the end of study visit they will be given the option to complete it at the visit. If the patient indicates that they do not wish to take the survey, they will be "withdrawn."

2.5 Endpoints

2.5.1 Primary Endpoints

1. Health Care Resource Consumption as measured by:
    a. Total costs billed for specific condition (HComp claims), as well as total costs billed
    b. Total health care visits and ER, Inpatient stays (hospitalizations), and office visits individually (HComp claims)
    c. Self-reported utilization (Stanford PERC Measure 4-item scale)
2. Health Self-Management as measured by:

a. Health Locus of Control (MHLC Form C 18-items)
b. Health Self-Efficacy (Stanford PERC Measure 6-item scale)
c. Patient Activation (Patient Activation Measure 13-items)

2.5.2 Secondary Endpoints

1. Health-related Quality of Life (SF-12 Short Form)
2. Biometric Measures (change in BP and/or blood glucose/HgA1c between Enrollment and Termination)
3. Physician Communication (Modified Medical Communication Competence Scale)
4. Medication Adherence (Morisky 8-item measure)

2.5.3 Exploratory Outcomes

1. Physical Activity/Exercise (GLTEQ 3-items)
2. Attitudes towards technology (Diffusion of Innovations, Personal Involvement Inventory)

(Only in intervention group)
3. Device/system usability (SUS 10-items)
4. Satisfaction with device (CSI 6-items)
5. Utility of Monitoring (TBD)
6. Motivation for tracking/compliance (TBD)
7. Correlations between wireless device readings/trends and primary and secondary endpoints

(Healthy Circles Google analytics and iforms)
8. Family engagement (HCircles invites to join care team)
9. Physician engagement (HCircles invites to join care team)
10. Education uptake (time spent on educational materials)
11. Data engagement (time spent viewing own data)

3.0 SUBJECT SELECTION

3.1 Number of Subjects

The study will enroll up to 250 individuals; 100 will be randomized to the monitoring group and 100 to the control groups.

Importantly, this pilot study is designed to leverage the full cohort (as a whole) to make a broader generalization as to the feasibility and potential utility of wireless monitoring across conditions and devices. The study is not powered, nor is its purpose, to definitively assess the utility of monitoring for each specific disease group. Data from each sub-group of participants, however (diabetes, hypertension, and arrhythmias), will be analyzed to identify trends for each disease group that will be used to inform future studies.

3.2 Nature of Study Population

Participants will be selected from among Scripps Health insured employees and family members whose healthcare benefits are administered via Health Comp.

3.3 Inclusion Criteria

1. Scripps Health insured employee or adult family member covered by Scripps Health plan
2. Ability to attend two visits (one at the beginning of the study and one at the end) at a Scripps facility
3. Computer and internet access, as well as ability to use e-mail and text messaging
4. Can grant permission for study staff to access medical records
5. Participating in Health Comp Disease Management program or willingness to join
6. English speaking
7. Within the past 12 months, a history of billing insurance for diagnostic codes consistent with diabetes, hypertension, and/or cardiac arrhythmia
8. 18 years and older
9. Willingness to use wireless devices, study iPhone, and learn to use the Healthy Circles platform.

3.4 Exclusion Criteria

1. Related to or household sharing with another study participant (if there are two or more people in one household that are eligible, the member that has the highest utilization will be invited to join first)
2. Change in living and/or employment situation that dictates the participant will no longer be covered by Scripps Health plan
3. Major surgery or extended trips in the next 6 months that may interfere with consistent use of monitoring device
4. Implanted ICD, pacemaker or implanted loop recorder or expected to undergo insertion during study
5. Arm circumference larger than that accommodated by Withings cuff
6. Unwilling or unable to grant informed consent
7. Pregnancy

3.5 Coding of Data Collected

All participant contact and data collection will be performed by Health Comp staff and Scripps Study Coordinators/Assistants. All data collected as part of the study, as well as medical and clinical information obtained from the patient's medical record will be used for study purposes only.

4.0 DISCONTINUED SUBJECTS

4.1 Study Withdrawal

Participants may withdraw at any time at their own request, or they may be withdrawn at any time at the discretion of the investigators for safety, or administrative reasons. If the subject requests to terminate their participation early, there will be no penalty or loss of benefits to which they are otherwise entitled. Any data that has been entered in the database will be included in the study analysis.

5.0 RISKS

Adverse Events

The likelihood of an adverse event with this intervention and study design is extremely low. Any concern regarding patient safety will be addressed by the study staff.

Risks Associated with Devices

- iBGStar – The risks associated with the glucose monitor include soreness to the finger used for fingersticks. The finger may become red and, very rarely, infected.
- Withings Blood Pressure Monitor –no risks.
- AliveCor ECG Monitor – no risks.

Psychological or Social Risks Associated with Loss of Privacy

While we believe that the risks to the participant associated with loss of privacy are low, we are unable to tell the participant exactly what all of the risks are. The participant's privacy is very important to us and we will use many safety measures to protect their privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that their identity will never become known. While the controlled-access databases specifically developed for this project will not contain information that is traditionally used to identify the participant, such as their name, address, and telephone number, people may develop ways in the future that would allow someone to link the participant's medical information back to them. There also may be other privacy risks that we have not foreseen.

Risks to Community or Group

Information on the participant's ethnic and geographical background will be included with other information about them in published research or a database developed for this study. In future studies, researchers may find that certain health problems appear more often in people from some ethnic groups than in people from other ethnic groups. This may make some people look down on the participant's ethnic group unfairly. Biology does not provide a reason for prejudice, but discrimination does exist. We will work to make sure that the ethnic or geographic identity of your community is described as carefully as possible in articles that project researchers write based on this research, but we cannot completely control how this information is described in publications that others write.

6.0 RISK ANALYSIS

Participants may or may not benefit from participating in this study, and may quit at any time. Study investigators, Scripps Translational Science Institute, Health Comp, Qualcomm, Scripps Health, and/or The Scripps Research Institute might benefit financially from this study. If any of these parties make a profitable product from the data collected or results obtained from this study, there is no plan to share any of the profits with the participants. The possible financial benefit to the institutions involved in the research will not affect the patient's safety or negatively impact the scientific quality of the study. If patients would like more information they may ask the study staff at Scripps or Health Comp.

The wireless monitoring data as well as the survey information collected from each participant will be labeled with a unique identifier. Study investigators at Health Comp and Scripps Translational Science Institute will keep the information that matches the code to traditionally used identifying information in a safeguarded database.

There is a low likelihood of any adverse events with this study, and wireless monitoring involves very little risk, therefore, the risk-benefit ratio is favorable.

6.1 Data Accessibility

The Principal Investigator, Sub-investigators, Research staff, and approved scientific research collaborators will have access to the participant's research information obtained in the context of this study. Only Health Comp and Scripps Translational Science Institute study staff will have access to participants' traditionally-used identifying information, such as name, address, and telephone number and medical information collected from the wireless monitoring system.

De-identified research information from analyses of the coded wireless monitoring data may be put into databases accessible by the Internet or other state-of-the-art standard method used by scientists to transmit data. The information in

this database will be available only to researchers who have received approval from a Data Access Committee composed of experts in the field.

The data may be made available to the Federal Food and Drug Administration, the National Institute of Health, the Department of Health and Human Services Agencies, Scripps Health, and The Scripps Research Institute, and other Institutional Investigators who have obtained permission from committees that review research to protect individuals.

6.2 Broad Data Sharing

This research is a collaborative effort and the data generated from this research may become available to other researchers in the future. This information could be put into scientific databases that are accessible to several research collaborators. Future researchers may use the information to study other questions about disease. The future researchers may include researchers at universities, hospitals, non-profit groups and other companies. Such researchers, just as with this project, will have to follow all the laws and guidelines that apply to biomedical research.

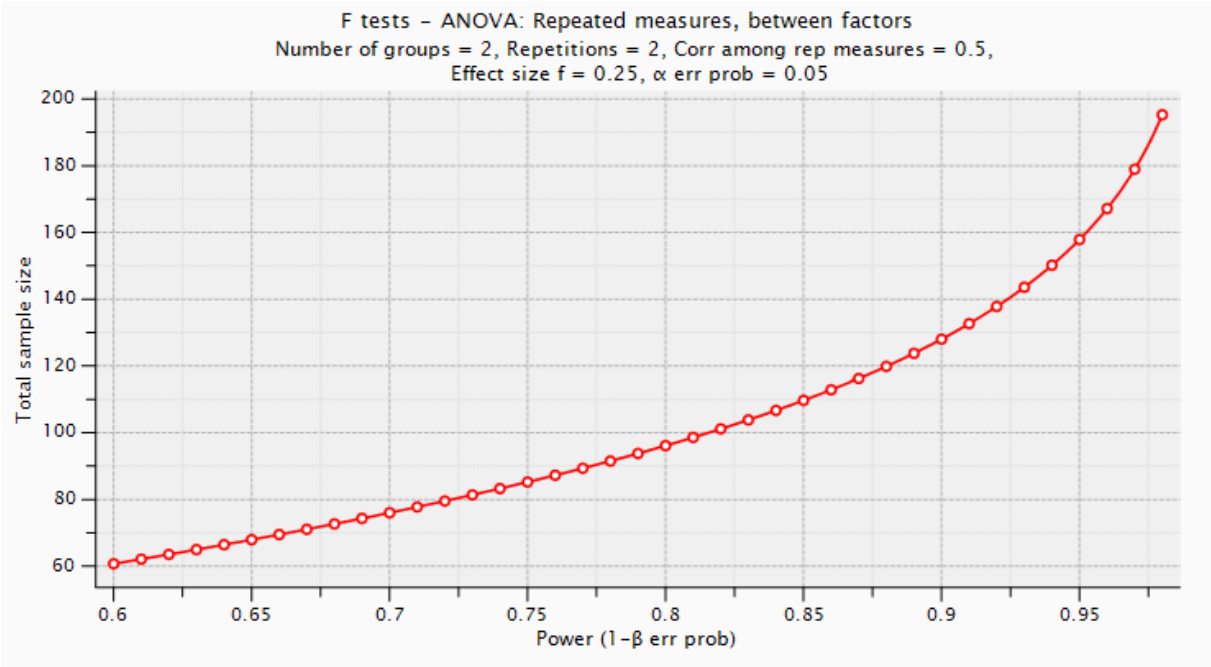
7.0 STATISTICAL METHODOLOGY

Data Analysis and Interpretation: We will analyze data from online web-based surveys, electronic medical records, and screening and enrollment visits, as well as data collected via the Healthy Circles software platform, Health Comp claims data, and possibly online portals specific to the devices used by patients for monitoring. We will leverage the benefits of a "gold standard" prospective randomized controlled design. Since randomization is being utilized, the treatment and control groups should not differ on important individual characteristics. In the event, however, that the groups are imbalanced on any key covariates, we will use propensity scores to control for this.

Importantly, we will compare outcomes:
1) Between the treatment and control groups, as well as
2) Within the treatment group between the pre-monitoring and on-monitoring periods for health resource utilization based on claims data.

At the end of the study, any change (e.g., reduction) in health service utilization achieved in the treatment group will be summarized statistically to yield a quantitative estimate of the potential effectiveness of wireless monitoring for lower health care costs and utilization rates. Our other primary and secondary endpoints will be treated in a similarly quantitative/statistical fashion.

Sample Size Justification for Pilot Study: Here we show the results of a power analysis to inform our sample size determination. As shown, to compare the difference in, e.g., clinic visits between the treatment and control groups using a repeated measures between factors ANOVA, at a sample size of 80 individuals in each group (conservatively accounting for attrition), we will have 95% power at alpha of 5% to detect a 1 visit difference between the groups assuming a standard deviation of 2 visits. The figure below depicts our statistical power as a function of sample size assuming 2 groups, 2 repeated measures (pre-monitoring and on-monitoring), an effect size of 0.25 and an alpha level of 0.05.



This study's target accrual is 100 individuals randomized to the wireless monitoring intervention and 100 individuals randomized to the control group. We will have the resources to potentially recruit our full target sample size within a 6-month period.

No interim analysis to adjust sample size is planned.

8.0 INFORMED CONSENT

Study staff at Health Comp will identify eligible participants. A Health Comp staff member will contact eligible participants and ask about their interest in participating in the study. If the participant is interested, he or she will be e-mailed a link to the Informed Consent form and asked to review and electronically sign the ICF. This will take place prior to any study procedure being performed as stated in the SOPRS policy 4.02. The participant will have as much time as needed to read, understand, and ask questions regarding the study and consent form. If the participant has any additional questions or concerns, they will be able to contact additional study staff for clarification. Once the participant signs the informed consent form, he/she will have an opportunity to print the consent form for his or her records.

The Principal Investigator, the Sub-Investigators, and the Clinical Research Coordinators have completed the informed consent module as required by SOPRS.

9.0 TERMINATION OF THE CLINICAL TRIAL

This will occur when the predetermined number of subjects has had all final assessments completed as outlined in the protocol, and all data have been analyzed. Based on the study design, the investigators do not anticipate a scenario that would trigger early termination.

10.0 RECORD RETENTION REQUIREMENTS

De-identified clinical information will be stored in a safeguarded database that is password protected, which will be located at STSI. The study information may be kept indefinitely, but the study investigators will be required to keep trial records for a period of up to two years.

11.0 MONITORING

11.1 Oversight of Study

This study will obtain Institutional Review Board Approval with Scripps Health.

11.2 Quality Assurance

During the study, collected data will be monitored for omitted data, gross data inconsistencies, illegible data, and deviations. Any deficiencies or deviations will be reviewed and any necessary action determined (e.g. data query). The data cleaning Cycle will be repeated until all data are considered clean. Incremental computer data back-up will be performed on a regular basis. Passwords will be issued to appropriate personnel to ensure confidentiality and protection of data.

11.3 Personnel Responsibilities

The Principal Investigator (PI) is an individual, who actually conducts a clinical investigation under whose immediate direction a product, i.e., drug or device, is administered or dispensed to a subject. The PI is the responsible leader for the team of individuals conducting the study. An exhaustive list of responsibilities is detailed in the Investigator's Agreement document.

11.3.1 Overview of Principal Investigator's Roles and Responsibilities

- Conduct the study according to ICH Guideline on Good Clinical Practice (E6), FDA requirements including 21CFR, Parts 11, 50, 54, 56, 812, and local requirements;
- Oversee all study-related medical decisions;
- Permit monitor(s) to inspect facilities and subject and study records;
- Permit FDA and sponsor inspections of facilities and records, if applicable;
- Maintain protocol adherence, comprehensive source documents, 100% product accountability, data validity;
- Submit protocol, informed consent, annual progress reports, final reports, and AE reports to the IRB and to the sponsor;
- Submit amendments to the protocol and informed consent to the IRB for approval, unless the changes reduce the risk to the subjects;
- Provide adequate medical care for any study AE and inform the subject when medical care is needed for any concurrent illness;
- Carefully explain the correct use of study product to the subject;
- Obtain written consent/assent;
- Document and inform ongoing subjects of revised information on the consent;
- Obtain and maintain IRB approval for the protocol and consent/assent;
- Maintain an adequate number of appropriately qualified staff and adequate facilities;
- Ensure all relevant clinical licensure is current for all study staff;
- Maintain the list of signatures documenting the delegation of study-related duties;
- Document and explain any deviation from the approved protocol;
- Review and sign eCRFs to ensure accuracy and completeness;
- Sign source notes to demonstrate review and agreement;
- Refrain from promoting study or study articles unless approved by STSI;

- Retain records for 2 years following completion of the study.

12.0 PUBLICATION POLICY

This trial will be registered with ClinicalTrials.gov, and as such will obtain a clinicaltrials.gov identifier.

12.1 Reporting

Study investigators will also seek to publish any findings in peer reviewed journals.

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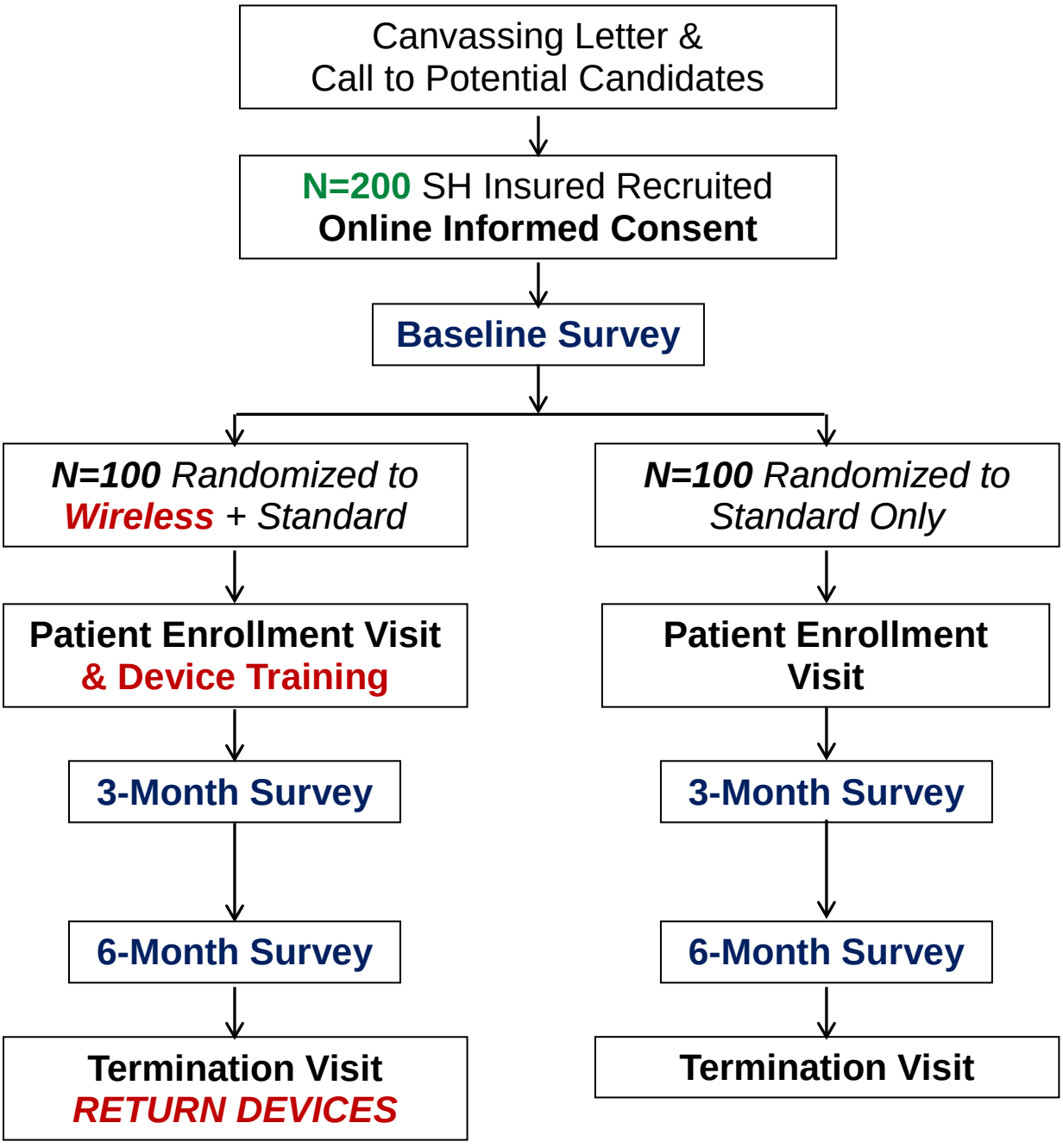
Appendices

Appendix 24: 6 Month E-Mail to Patients

Appendix 1: Study Diagram

Wired for Health Study Design



Appendix 2: Initial Letter Sent to Patients with High Utilization

Patient already participating in Disease Management Program:

Dear Member,

Thank you for your continued participation in the Disease Management program. We are pleased to be a part of your health care team.

We are sending you this letter to let you know about the new Scripps **Wired for Health Study** and to see if you might have interest in participating. This unique study is focusing on individuals who have diabetes, high blood pressure or a heart arrhythmia. It will test whether individuals who use remote wireless monitoring devices are better able to control their condition and decrease the cost of their health care over a six month period.

Study participants will be randomly assigned to either the control or monitoring group. Both groups will meet with a study staff member, complete health questionnaires and provide information about their current health conditions. The monitoring group will be provided with up to three devices. These devices include a blood pressure monitor, blood sugar monitor and/or heart monitor based on their current health conditions. All three devices will connect to an iPhone that will also be provided to the monitoring group for the duration of the study

The **Scripps Wired for Health Study** is voluntary and will not cost you anything to participate. If you are interested in more information or signing up, please call a Health Comp Nurse at 1-800-442-7247 ext. 2507 or email them at wellness@healthcomp.com If we don't hear from you a Nurse will call you in 2-4 weeks to see if you are interested or have any questions.

We thank you for your time and wish you continued good health.

Sincerely,

Wellness Management
Phone: (800) 442-7247
Email: Wellness@HealthComp.com

Patient not yet participating in Disease Management Program:

Dear Member,

As a Nurse with HealthComp, I want to provide you with information on our Disease Management program. This is a free, voluntary program provided to you through your Scripps health plan.

The Disease Management program is designed to partner with you to help you achieve your health goals. You will have access to a nurse that can help answer questions and will check in with you to see how you are feeling. We can also work with you to develop a plan to introduce healthy changes into your lifestyle and provide you with educational materials about your current health conditions.

As part of the Disease Management program you may also be asked to participate in the **Scripps Wired for Health study**. The study is focusing on individuals who have diabetes, high blood pressure or a heart arrhythmia. It will test whether individuals who use wireless remote monitoring devices are better able to control their condition and decrease the cost of their health care over a six month period.

Study participants will be randomly assigned to either the control or monitoring group. Both groups will meet with a study staff member, complete health questionnaires and provide information about their current health conditions. The monitoring group will be provided with up to three devices. These devices include a blood pressure monitor, blood sugar monitor and/or heart/ECG monitor based on current health conditions. All three devices will connect to an iPhone that will also be provided to the monitoring group for the duration of the study.

Both the Disease Management program and **Scripps Wired for Health Study** are voluntary and will not cost you anything to participate. If you are interested in more information or signing up please call a Health Comp Nurse at 1-800-442-7247 ext. 2507 or email them at wellness@healthcomp.com. If we don't hear from you a Health Comp Nurse will call you in 2-4 weeks to see if you are interested or have any questions.

We thank you for your time and wish you continued good health.

Sincerely,
Wellness Management
Phone: (800) 442-7247
Email: Wellness@HealthComp.com

Patient Outreach Call: Scripps Wired for Health Study

Not Currently Enrolled in DM Program
My name is _____ and I'm calling from Health Comp on behalf of Scripps Health. I want to talk to you about a free and confidential program Scripps is offering designed to help you manage your health goals. The Wellness and Disease Management Program will provide you with access to a nurse that can offer information, help answer questions and give you some reminders on a few things you may not be aware of.

Currently Enrolled in the DM Program
My name is _____ and I am calling to say thank you for your participation in the HealthComp Wellness and Disease Management program offered to you by Scripps Health. I hope that you have found it to be helpful and beneficial to your health goals.

The advice given is not meant to replace the care of your medical provider, but rather a complement to that care. We encourage you to establish a relationship with a primary care provider and see them as needed for all preventive and routine care based on your age, gender and condition**.**

Continue Here to Discuss Study
As part of the Disease Management Program, you may be asked to participate in the Scripps Wired for Health Study. We are enrolling patients who have high blood pressure, diabetes, and/or heart arrhythmias. We're going to test whether individuals who use wireless health devices are better able to control their condition and perhaps use the health care system less often

Are you interested in participating or learning more about either of these programs?

If they express an interest in Scripps study, complete the Screening form.

[If not eligible:
I'm sorry, but you are not eligible to participate in the Scripps study. However, you may still participate in Disease Management Program.]

If eligible:
Do you have 10-15 minutes right now to hear more about the study?

There has been some research which shows that when people take their own health readings at home, they are better able to control their disease, stay healthier and go to the doctor less often. In this study, we are testing wireless devices that you can use at home for diabetes, high blood pressure and cardiac arrhythmias. You will be given an iPhone for use during the study and your recordings will be stored and displayed on the phone.

We will be testing how easy it is to use these devices and whether or how easy it is to fit in your daily schedule.

There are 2 groups in this study and you will be randomly assigned (like flipping a coin) to either the:

- Group A: Disease Management program + devices
- Group B: Disease Management program only

Both groups will meet with a study coordinator 1 time at the beginning of the study and 1 time at the end. These visits will take 30-60 minutes. You will have your blood pressure taken and if you have diabetes, your blood sugar will be taken.

The monitoring group will be given and trained on up to 3 devices: a blood pressure monitor, blood sugar monitor, and a heart monitor, depending on your health. All three devices will connect to an iPhone that will also be provided to the monitoring group for the duration of the study. The iPhone will be programmed so that it can only be used for study purposes and will be returned at the end of the study, along with the study devices. You will be asked to use the devices for a period of six months.

If you are in the device group you will be contacted by phone 7-10 days after your visit with the study coordinator to confirm devices are working properly.

The study will last for 6 months from the time of your visit with the study coordinator. You'll get an e-mail about 3 months after that visit and be asked to complete another survey online. You'll also be asked to complete a final survey at 6 months. The questions will be about your health, how often you go to the doctor, your feelings toward new technology.

As a part of the Disease Management program, the nurses at Health Comp will call you periodically to see how you're doing. We will review with you what if any deficits may be outstanding and we will provide you with some education both verbally and written on your chronic health. If communication with your provider is necessary we are happy to contact them.

The study is totally voluntary and you can quit at any time.

Everyone who is participating in the study is either a Scripps employee or family member. The employee will receive a $20 gift card and 10 Scripps Health Wellness points at the completion of the study. As you may know, if an employee earns 15 Wellness points in a calendar year, they may be eligible for a reduction in health insurance costs.

You may or may not benefit from participating in this study. If you're in the device group, you'll be participating in the Disease Management program as well as be able to see your reading on your iPhone. If you're in the other group, you'll still be able to benefit from Health Comp's Disease Management program.

Do you think you'd like to participate?

I have some questions to ask to confirm that you are eligible.

WFH Screening Contact

Date of Contact: _____ Time of Contact: _____ AM PM

Name: _____ Member ID: _____

Gender: Male ____ Female _____ Year of Birth: _____ Age: _____

Patient is: Employee _____ Spouse _____ Dependent _____

Outcome of Call:

- ❑ Interested in both DM program and study. Completed screening form
- ❑ Not interested in either DM program or study (requests no further contact)
  - o Reason: _____
- ❑ Interested in DM but not study
  - o Reason: _____

WFH Screening Form

Do you have any the following?

High Blood Pressure or Hypertension □ Yes □ No	Diagnosed by doctor? □ Yes □ No	Year diagnosed _____	On medication for this condition? □ Yes □ No
Non-Insulin Dependent Diabetes □ Yes □ No	Diagnosed by doctor? □ Yes □ No	Year diagnosed _____	On medication for this condition? □ Yes □ No
Insulin Dependent Diabetes □ Yes □ No	Diagnosed by doctor? □ Yes □ No	Year diagnosed _____	On medication for this condition? □ Yes □ No
Cardiac Arrhythmia (heart rhythm problems) □ Yes □ No	Diagnosed by doctor? □ Yes □ No	Year diagnosed _____	On medication for this condition? □ Yes □ No

Inclusion Criteria: In order to be eligible, patient must answer 'Yes' to all:

□ Yes □ N	Are you a Scripps insured employee or family member?
□ Yes □ N	Do you have high blood pressure, diabetes and/or heart arrhythmias?
□ Yes □ N	Do you have computer and internet access, as well as ability to use e-mail and possibly text messaging?
□ Yes □ N	Are you already participating in or willing to join the Health Comp Disease Management program?
□ Yes □ N	Are you 18 years of age or older?

Exclusion Criteria: In order to be eligible, patient must answer 'No' to all:

□ Yes □ No	Do you anticipate any changes over the next 6 months in that you would no longer be covered under Scripps insurance (leaving job, retiring, etc.)?
□ Yes □ No	If you are assigned to the monitoring group, do you have any upcoming surgery, extended trips or any other reason that you may not be able to regularly use the device assigned to you?
□ Yes □ No	Are you related to or sharing a household with anyone participating in this study?
□ Yes □ No	Are you pregnant?

For patients diagnosed with cardiac arrhythmia only:

□ Yes □ No	Do you have an implanted ICD, pacemaker or implanted loop recorder, or expecting to undergo insertion during the next 6 months?

What Scripps facility would be most convenient for you?

- ❑ Clinic location on N. Torrey Pines Road
- ❑ Chula Vista
- ❑ Mercy San Diego

In general, what is the best time of the day for a 1 hour appointment?

- ❑ Morning (9:00-12:00)
- ❑ Afternoon (1:00-5:00)
- ❑ Evening (5:00-7:00)

Do you currently use a smart phone? □ Yes □ No If yes, what kind?

- ☐ iPhone
- ☐ Android (Samsung, Motorola, Kyocera, etc.)
- ☐ Blackberry

If yes, how long have you been using it? _____.

If no, do you have a cell phone? What kind? _____

Do you anticipate any problems with carrying 2 phones and learning how to use an iPhone? □ Yes □ No

Have you had any previous experience with using a home health monitoring device? □ Yes □ No
If yes, what device and for how long? _____ device for _____ months

Based on your diagnosis of [hypertension, NIDDM, IDDM or arrhythmia], are you willing to do home measurement on this schedule? □ Yes □ No

[Circle device and tell patient expected frequency of measurement.]

Device	Frequency of Measurement
HTN: Withings BP	2 x per day, 3 days per week, 1st one in a.m.
NIDDM: iBG Star	1 x per day (premeal), 3 days per week
IDDM: iBG Star	4 x per day (premeal, with 4th reading at bedtime, 2 hours after last meal/dinner), every day
Arrhythmia: Alive Cor ECG	if symptomatic

Phone #s: Home: _____ Cell: _____

E-mail address You Check Most Frequently: _____

The first thing that has to happen is you need to sign a consent form for the study. We are doing this on line so you can read it and sign it on your computer. You don't have to print it out. After we're done talking, you will be emailed a link to the Informed Consent form. Please read it carefully. There will be a phone number included so if you have any questions regarding the study, you should call and make sure you get your questions answered before you sign the consent form. You will get instructions on how to electronically sign the form. After you have signed it and clicked "Submit," you will be automatically directed to a health survey to complete on the computer.

After you have signed the Informed Consent form and completed the health survey, you will get a call from one of the study coordinators at Scripps to schedule your initial visit . This visit can be done at a Scripps facility near Green Hospital, Scripps Mercy Hospital or Scripps Chula Vista Hospital. If you decide not to participate before your appointment, we will cancel the appointment and there will be no more contact regarding the study. Which location is most convenient for you? When would be a good day/time for this appointment?

You'll receive a notice by e-mail confirming this appointment and showing you how to change it, if you need to.

Thank you so much for your interest. You will receive an e-mail within 2 days with instructions about reading and signing the consent form.

Thanks again.

Appendix 4

Overview of Health Comp's Disease Management Program,
Sample Letter and Educational Materials

HealthComp
Third Party Administrators
Wellness Management

Overview of Disease Management Program

The goal of the Disease Management program is to assist patients in making health behavior changes. We feel like the best way to promote a change is with "one on one" nurse to patient intervention. We follow the process listed below, but the biggest contributing factor in creating a change is the trust and integrity that is built in this relationship.

An algorithm is used to rank risk indicators associated with the group's population:

1. 3 Major disease states are managed
    - Heart arrhythmia
    - Cardiac
    - Diabetes
2. Claims and pharmacy data are reviewed
3. Outreach Call is made to patient
4. Deficit List is completed
    - Unfulfilled deficits are identified
    - Intervention plan is organized
    - Educational material is sent based on care plan
5. Summary of findings is sent to the patient
6. Repeat this process starting with 3 every 3 to 6 months. The employee can stay in the program indefinably.
7. We may contact the treating provider to advice of those missing deficits and request the provider review the patients chart.

Mailing Address: P.O. Box 45018, Fresno, CA 93718-5018
Phone: (800) 755-7247 Fax: (559) 243-7012

HealthComp
Third Party Administrators
Wellness Management

Dear :

As a Nurse with the HealthComp Wellness Management Program, I want to provide you with information on this voluntary Program, which is a free benefit provided through your health plan.

The goal of the Wellness Management Program is to act as a resource for you and your family. We consist of a Wellness team that includes nurses, pharmacists, and other ancillary staff working on your behalf. We assist you by answering questions, sending health information, reviewing medications, or by acting as a patient advocate for you with your physician. However, we are in no way a replacement to your health care provider, but rather an additional resource for you.

We use national guidelines of care to ensure that you are within acceptable health standards. In light of that, we have noticed there may be an incomplete record of your care, as noted in the following pages. These recommendations are subject to your specific benefits plan and deductibles. ***Only the areas marked with an "X" are relevant to you.*** If we are in error, please contact us to clarify. Because our intent is to ensure that you are receiving the best care possible, we advise that you take this letter with you to your next doctor visit in order to discuss the following recommendations.

If you have any questions or are unsure about a medication, medical procedure, or are simply curious about how to better manage your health, please contact me at the number listed below. I thank you for your time and wish you continued good health.

Sincerely,

Your Wellness Team

Mailing Address: P.O. Box 45018, Fresno, CA 93718-5018
Phone: (800) 755-7247 Fax: (559) 243-7012

HealthComp
Third Party Administrators
Wellness Management

Clinical Recommendations based on National Care Guidelines			
Clinical Recommendations for Diabetes Care			
Lab tests		**Pharmacological Management**	
☐	Hemoglobin A1C done at least every six months (blood test to check how your blood sugar levels have been on average over the last 3 months)	☐	Cholesterol lowering medication for those greater than 40 years of age and/or with an LDL level (bad cholesterol) of 135 or greater (medication to decrease risk of cardiovascular disease)
☐	Lipid Profile annually (blood test to screen for high cholesterol and possible coronary artery disease, very common with diabetes)		
☐	Urine Microalbumin annually (urine test to evaluate kidney function)	☐	Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) (medication used to protect kidneys)
☐	Serum Creatinine annually (blood test to evaluate your kidney function)	☐	
☐	Liver Function Tests (LFT's) annually if on certain cholesterol lowering medications (blood test to evaluate liver function)	**Miscellaneous Exams**	
		☐	Semiannual Dental Exam (to evaluate for tooth decay and periodontal disease)
Vaccines			
☐	Seasonal Flu Vaccine (to prevent the Flu)	☐	Annual Eye Exam (to evaluate for diabetes related eye disease and risk for blindness)
☐	Pneumococcal Vaccine every 5-10 years (to prevent bacterial pneumonia)	☐	Annual Foot Exam (to evaluate for diabetes related nerve damage and skin integrity)
Clinical Recommendations for Heart Disease Management			
Lab tests		**Pharmacologic Management**	
☐	Congestive Heart Failure-Annual Cholesterol Test (blood test to evaluate cholesterol levels)	☐	Congestive Heart Failure-Beta Blocker *and* Vasodilator, or ACE-I/ARB (medication to decrease the workload of the heart)
☐	Congestive Heart Failure-Annual Metabolic Panel (blood test to check for changes in your blood chemistry due to medications)	☐	Coronary Artery Disease or Dyslipidemia-Cholesterol-lowering medication (medication to prevent elevated cholesterol levels)
☐	Coronary Artery Disease or Dyslipidemia-Annual Cholesterol Test (blood test to evaluate cholesterol levels)	☐	Post Heart Attack-on a Cholesterol-lowering medication (to prevent high cholesterol levels)
		☐	Post Heart Attack-on a Beta Blocker (medication to decrease the workload of the heart)
☐	Coronary Artery Disease-Annual Glucose Test (blood test to evaluate risk of diabetes)	☐	Daily Baby Aspirin Men age 45-79 and Women age 55-79 (to prevent heart attack)
☐	Liver Function Tests (LFT's) annually if on certain cholesterol lowering medications (blood test to evaluate liver function)	☐	Atrial Fibrillation-Anticoagulation (medication to prevent strokes)
☐	Atrial Fibrillation-Monthly Protime (blood test to evaluate clotting time related to warfarin (Coumadin) use)	☐	Atrial Fibrillation-on a Beta Blocker or Calcium Channel Blocker (medication to maintain heart rate)
Vaccines		**Miscellaneous Exams/Recommendations**	
☐	Seasonal Flu Vaccine (to prevent the Flu)	☐	Annual Cardiac Stress Test (treadmill test to evaluate heart function and disease)
☐	Pneumococcal Vaccine every 5-10 years (to prevent bacterial pneumonia)		

Mailing Address: P.O. Box 45018, Fresno, CA 93718-5018
Phone: (800) 755-7247 Fax: (559) 243-7012

DIABETES

HealthComp®
Third Party Administrators
Wellness Management

Plan for Wellness

Managing your blood sugar

If you have diabetes, you should know the basic steps for managing it so that you stay as healthy as possible. Poorly managed diabetes can lead to many health problems.

All people with diabetes should know:

- How to recognize and treat low blood sugar (hypoglycemia)
- How to recognize and treat high blood sugar (hyperglycemia)
- Diabetes meal planning
- How to monitor your blood sugar
- What to do when you are sick
- Where to buy diabetes supplies and how to store them
- What checkups you may need

If you take insulin, you should also know:

- How to give yourself insulin
- How to adjust your insulin doses and foods you eat if you exercise

Check Your Blood Sugar Often

Checking your blood sugar levels often and writing down the results will tell you how well you are managing your diabetes. Talk to your doctor and diabetes educator about how often.

Usual times to test your blood sugar are before meals and at bedtime.

- *Other times to check* your blood sugar may be:
- After you eat out, especially if you have eaten foods you do not normally eat
- If you feel sick
- Before and after you exercise
- If you have a lot of stress
- If you eat too much
- If you are taking new medicines
- Keep a record for yourself and your doctor or nurse. This will be a big help if you are having problems managing your diabetes.

Recommended Blood Sugar Targets

For people with type 1 diabetes, the American Diabetes Association recommends the following blood sugar targets. Talk to your doctor and diabetes educator about these goals.

Before meals, your blood sugar should be:

- From 90 - 130 mg/dl for adults
- From 90 - 130 mg/dl for children 13 - 19 years old
- From 90 - 180 mg/dl for children 6 - 12 years old
- From 100 - 180 mg/dl for children under 6 years old

After meals (1 - 2 hours after eating), your blood sugar should be:

- Less than 180 mg/dl for adults

At bedtime, your blood sugar should be:

- From 90 - 150 mg/dl for adults
- From 90 - 150 mg/dl for children 13 - 19 years old
- From 100 - 180 mg/dl for children 6 - 12 years old
- From 110 - 200 mg/dl for children under 6 years old

For people with type 2 diabetes, the American Diabetes Association recommends the following blood sugar targets. Talk to your doctor and diabetes educator about these goals.

Before meals, your blood sugar should be:

- From 70 - 130 mg/dl for adults

After meals (1 to 2 hours after eating), your blood sugar should be:

- Less than 180 mg/dl for adults

HealthComp Wellness Management
P.O. Box 45018
Fresno, CA 93718

800-755-7247
www.healthcomp.com
wellness@healthcomp.com

Content Source: http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000086.htm

Appendix 5

SCRIPPS WIRED FOR HEALTH STUDY - BASELINE SURVEY

I. Demographics

1. What is your gender?
    a. Male
    b. Female

2. What year were you born? (pull down)

3. What is your ethnicity? (pull down: Caucasian, African-American, Hispanic/Latino, Asian, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, Other)

4. What is your marital status? (pull down: married, single, divorced, separated)

5. What is the highest level of education you've completed? (pull down: completed 11 or fewer years, graduated from HS or GED completed, graduated from 2-year college, graduated from 4-year college, completed some post-college education, completed Master's degree, completed professional or Ph.D.)

This study is about health care costs, so we would like to better understand your financial situation and the amount of money you have available to spend on your health care.

6. What is your approximate household income? (pull down: under 25k, 25-49k, 50k-99k, 100k-149k, 150k-199k, 200k-249k, 250k-299k, 300k or more)

7. How many people live in your house? (pull down: just me, 1, 2, 3, 4, 5, 6, more than 6)

8. How many people are financially dependent on you (i.e., your number of "dependents")? (pull down: just me, 1, 2, 3, 4, 5, 6, more than 6)

9. Please estimate your approximate household monthly disposable income (i.e., the amount of money you have to spend or save after paying all your bills)? (pull down)

10. What were your approximate out-of-pocket healthcare expenses last year? (pull-down)

II. Health History

1. How is your health? (pull down: very good, good, average, poor, very poor)

2. Do you currently use tobacco (i.e., cigarettes, cigars, pipe, chewing tobacco)? (yes/no)

3. If no, have you previously used tobacco? (yes/no)

4. If you are a current or previous user of tobacco, how many times per week do you/did you use it?

5. If you are a current or previous user of tobacco, for how many years have you/did you use it? (pull down)

6. Do you drink alcohol? (yes/no)

7. If no, was there a previous time during which you drank alcohol? (yes/no)

8. If you are a current or previous drinker, how many drinks per week do you/did you have?

9. If you are a current or previous drinker, for how many years have you/did you drink? (pull down)

10. Have you ever been told by a doctor or other health professional that you have high blood pressure or hypertension? (yes, no, not sure)

11. Have you ever been told by a doctor or other health professional that you have diabetes? (yes, no, not sure)

12. Have you ever been told by a doctor or other health professional that you have pre-diabetes? (yes, no, not sure)

13. Have you ever been told by a doctor or other health professional that you have an abnormal heart rhythm? (yes, no, not sure)

14. Please list any and all additional health conditions that you have been told by a doctor or other health professional that you currently have.

15. Please list all of the medications for which you currently have a prescription from a doctor or other health professional.

III. Health Literacy (single item)

How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy? (pull down: Never, Rarely, Sometimes, Often, and Always)

IV. Perceived Health Services Utilization (PERC)

1. Please answer the following:

   a. In the past 6 months, how many times did you visit a physician? Do **not** include visits while in the hospital or to a hospital emergency room. Fill in with "0" or another number. ____times

   b. In the past 6 months, how many times did you go to a **hospital** emergency room? Fill in with "0" or another number. ____times

   c. How many different **times** did you stay in a hospital **overnight** or longer in the past 6 months? Fill in with "0" or another number. ____times

   d. How many total **nights** did you spend in the hospital in the past 6 months? Fill in with "0" or another number. ____nights

V. Health Locus of Control (MHL Form C)

Each item below is a belief statement about your medical condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer **EVERY ITEM** and that you circle **ONLY ONE** number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

		Strongly Disagree	**Moderately Disagree**	**Slightly Disagree**	**Slightly Agree**	**Moderately Agree**	**Strongly Agree**
1	If my condition worsens, it is my own behavior which determines how soon I will feel better again.	1	2	3	4	5	6
2	As to my condition, what will be will be.	1	2	3	4	5	6
3	If I see my doctor regularly, I am less likely to have problems with my condition.	1	2	3	4	5	6
4	Most things that affect my condition happen to me by chance.	1	2	3	4	5	6
5	Whenever my condition worsens, I should consult a medically trained professional.	1	2	3	4	5	6
6	I am directly responsible for my condition getting better or worse.	1	2	3	4	5	6
7	Other people play a big role in whether my condition improves, stays the same, or gets worse.	1	2	3	4	5	6
8	Whatever goes wrong with my condition is my own fault.	1	2	3	4	5	6
9	Luck plays a big part in determining how my condition improves.	1	2	3	4	5	6
10	In order for my condition to improve, it is up to other people to see that the right things happen.	1	2	3	4	5	6
11	Whatever improvement occurs with my condition is largely a matter of good fortune.	1	2	3	4	5	6
12	The main thing which affects my condition is what I myself do.	1	2	3	4	5	6
13	I deserve the credit when my condition improves and the blame when it gets worse.	1	2	3	4	5	6
14	Following doctor's orders to the letter is the best way to keep my condition from getting any worse.	1	2	3	4	5	6
15	If my condition worsens, it's a matter of fate.	1	2	3	4	5	6
16	If I am lucky, my condition will get better.	1	2	3	4	5	6

17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself.	1	2	3	4	5	6
18	The type of help I receive from other people determines how soon my condition improves.	1	2	3	4	5	6

VI. Health Self-Efficacy (SE for Managing Chronic Disease 6-Item Scale)

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

not at all | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

not at all | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

not at all | | | | | | | | | totally
confident 1 2 3 4 5 6 7 8 9 10 confident

VII. Patient Activation (Me and My Health)

INSTRUCTIONS: For each statement below please mark an X in the box to the right that best describes how much you disagree—agree with the statement as it applies to you personally.

There are no right or wrong answers. Your answers should be what is true to you and not just what you think the doctor wants you to say.

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. When all is said and done, I am the person who is responsible for managing my health condition.				
2. Taking an active role in my own health care is the most important factor in determining my health and ability to function.				
3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition.				
4. I know what each of my prescribed medications do.				
5. I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself.				
6. I am confident I can tell a doctor concerns I have even when he or she does not ask.				
7. I am confident that I can follow through on medical treatments I need to do at home.				
8. I understand the nature and causes of my health condition(s).				
9. I know the different medical treatment options available for my health condition.				
10. I have been able to maintain the lifestyle changes for my health condition that I have made.				
11. I know how to prevent further problems with my health condition.				
12. I am confident I can figure out solutions when new situations or problems arise with my health conditions.				
13. I am confident that I can maintain lifestyle changes, like diet and exercise, even during times of stress.				

VIII. Health-Related Quality of Life (SF12)

For each of the following questions, please circle the number that best describes your answer.

1. In general, would you say your health is:
_____ Excellent (1)
_____ Very Good (2)
_____ Good (3)
_____ Fair (4)
_____ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
_____ Yes, Limited A Lot (1)
_____ Yes, Limited A Little (2)
_____ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:
_____ Yes, Limited A Lot (1)
_____ Yes, Limited A Little (2)
_____ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
_____ Yes (1)
_____ No (2)

5. Were limited in the KIND of work or other activities:
_____ Yes (1)
_____ No (2)

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:
_____ Yes (1)
_____ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:
_____ Yes (1)
_____ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

_____ Not At All (1)
_____ A Little Bit (2)
_____ Moderately (3)
_____ Quite A Bit (4)
_____ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

10. Did you have a lot of energy?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

11. Have you felt downhearted and blue?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

IX. Physician Communication

The purpose of this questionnaire is to obtain your views about your communications with your **physician (the one you see most often) about your medical problems.** Please show how strongly you agree or disagree with these statements by **checking the box that best fits your views.**

		Strongly Disagree	Disagree	Slightly Disagree	Not Sure	Slightly Agree	Agree	Strongly Agree
I DO A GOOD JOB OF:								
1.	Explaining my medical problem.							
2.	Describing the symptoms of my medical problem(s).							
3.	Answering the doctor's questions thoroughly.							
4.	Answering the doctor's questions honestly.							
5.	Letting the doctor know when I didn't understand something.							
6.	Getting answers to my questions.							
7.	Getting all the information I need.							
MY PHYSICIAN EXPLAINS THE FOLLOWING TO MY SATISFACTION:								
1.	Explaining what my medical problems are.							
2.	Explaining the possible causes of my medical problems.							
3.	Explaining what I may be able to do to get better.							
4.	Reviewing or repeating important information.							
5.	Making sure I understand his/her explanations/directions.							
6.	Using language I can understand.							
7.	Encouraging me to ask questions.							
Please indicate how strongly you agree or disagree with these statements:								
	Overall, I am satisfied with my physician's communication regarding my medical problems.							

X. Medication Adherence (Morisky 8-Item)

Question	Yes	No
1. Do you sometimes forget to take your medicine?		
2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?		
3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your medicine?		
5. Did you take all your medicines yesterday?		
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?		
7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

8. How often do you have difficulty remembering to take all your medicine?

__ A. Never/rarely

__ B. Once in a while

__ C. Sometimes

__ D. Usually

__ E. All the time

XI. Exercise (GLTEQ)

1. During a typical 7-Day period (a week), how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

	Times Per Week
a) STRENUOUS EXERCISE (HEART BEATS RAPIDLY) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	
b) MODERATE EXERCISE (NOT EXHAUSTING) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	
c) MILD EXERCISE (MINIMAL EFFORT) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	

2. During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

OFTEN _____ SOMETIMES _____ NEVER/RARELY _____

XII. Use of Innovations

1. Please answer the following questions regarding your thoughts, views, and feelings about **new medical tests, treatments, and devices.**

		strongly disagree	disagree	neutral	agree	strongly agree
1.	If I heard of a new medical test, treatment, or device I would try to find out more about it					
2.	Among my friends, I am usually one of the first to find out about and/or utilize a new medical test, treatment, or device					
3.	In general, I am hesitant to undergo or utilize a new medical test, treatment, or device					

2. Please answer the following questions regarding your thoughts, views, and feelings about **the use of medical devices that can be used at home** to monitor various aspects of your health, including blood pressure, blood sugar, and heart rhythms.

		strongly disagree	disagree	neutral	agree	strongly agree
1.	The use of at-home medical devices for health monitoring is consistent with my approach to my health					
2.	The use of at-home medical devices for health monitoring fits well with my values and goals					
3.	The use of at-home medical devices for health monitoring is hard to understand					
4.	The use of at-home medical devices for health monitoring has many different parts					
5.	The use of at-home medical devices for health monitoring can help me stay healthier compared to other strategies, like seeing my doctor more often					

3. Do you currently own and use a cell phone?

4. If yes, is your phone a Smart Phone?

5. If yes, is your phone an i-Phone?

6. Please answer the following:

   To me, new digital technologies like the Smart Phone are:

b.	important	___:___:___:___:___:___:___	unimportant
c.	boring	___:___:___:___:___:___:___	interesting
d.	relevant	___:___:___:___:___:___:___	irrelevant
e.	exciting	___:___:___:___:___:___:___	unexciting
f.	means nothing	___:___:___:___:___:___:___	means a lot to me
g.	appealing	___:___:___:___:___:___:___	unappealing
h.	fascinating	___:___:___:___:___:___:___	mundane
i.	worthless	___:___:___:___:___:___:___	valuable
i.	involving	___:___:___:___:___:___:___	uninvolving
j.	not needed	___:___:___:___:___:___:___	needed

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Subject to the terms of the Download License as supplemented by this Supplementary License, User is granted a non-transferable, non-exclusive and free license for the use of the iBGStar® Wired for Health application on the iPhone, that User controls as permitted by the Download License as supplemented by this Supplementary License including, but not limited to, the Usage Rules set forth in the App Store Terms of Services referenced in the Download License. You may use the iBGStar® Wired for Health application for personal use. The iBGStar® Wired for Health application has been developed by Sanofi or its licensors and is protected by copyright and may not be reproduced or used without the expressed written permission of Sanofi US. Making additional copies of the software, or enabling others to use your registration code(s) or serial number(s), if any, is strictly prohibited. It is also prohibited to duplicate the software by any other means including electronic transmission. The software also contains trade secrets and you may not decompile, reverse engineer, disassemble or otherwise reduce the software to human-perceivable form or disable any functionality which limits the use of the software. You may not modify, adapt, translate, rent or sublicense (including offering the software to third parties on an application service provider or time-sharing basis), assign, loan, resell for profit, or distribute the software, disks or related materials or create derivative works based upon the software or any part thereof, without the express written permission of Sanofi US.

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Privacy Policy

In the context of the WFH Study, Sanofi is not involved in the storage, management or analyze of the users' medical data transmitted by the application. Sanofi US will not have access to any personal information. Sanofi US encourages the persons involved in the WFH clinical study to refer to the data privacy provisions of the study enrollment documentation (HIPAA Authorization).

Breach of Security

User acknowledges that Sanofi or its licensors, in their sole discretion, have taken necessary measures to ensure the privacy, integrity and security of the data entered by the user when transmitting that data between the user's device(s) such as iPhone or a web browser and the servers that will host/store the data. Despite these security and privacy measures, it is possible that there can be a breach in the data security resulting from non-malicious actions of Sanofi or its licensors and/or malicious actions of external parties. Neither Sanofi nor its licensors shall be responsible for such effects, and neither Sanofi nor its licensors shall have any obligation to furnish any maintenance and support services with respect to the iBGStar® Wired for Health application.

Withings Terms of Use of Services

Last update: 01/06/2011

Welcome to the Withings site: www.withings.com is a Site offered by Withings, a simplified stock company (SAS) with 2,551,824 euros in capital, whose registered office is located at 20 rue Rouget de Lisle 92130 ISSY LES MOULINEAUX, registered in the Nanterre Companies and Trade Registry under number 504 787 565.

Please read these Terms of Use carefully; print them up and keep a copy.

Your personal data are protected. The confidentiality of your personal information is essential; we are determined to protect it. Please read the Privacy Rules page for more details.

Definition

The following words and expressions beginning with a capital letter will have the following meanings:

The **"Applications"**: are the digital contents that Withings offers to the User for consultation or download. This software has been developed by Withings. These Applications support the Service;

The **"Account"**: is a strictly personal space created by the User when registering on the Site, enabling him to access the Service;

The **"Interface"**: is a remote display making it possible to utilise all of the Product's functions;

The **"Smartphone"**: is a latest-generation intelligent mobile telephone;

The **"Product"**: is the **"Body Scale"** online object, the **"Blood Pressure Monitor"** online object or the **"Babyphone"** online object;

The **"Service Provider"** or **"Withings"** or **"we/us"**: is Withings, the company that provides the Service;

The **"Service"**: is (i) the platform allowing access to the Product interface via certain smartphones, or (ii) the platform allowing access to the Product interface via the Site, or (iii) the platform making it possible to obtain software to be integrated into the Product, or (iv) the platform allowing installation of the Product from a computer, or (v) the platform allowing access to the Site;

The **"Site"**: is the Web site http://www.withings.com;

The **"User"** or **"you"**: is the person registered on the Site who uses the Service.

Purpose

These Terms of Service are Intended to define the contractual relationship entre le Service Provider and the User.

Acceptance

In order to access the Service, the User must register on the Site by creating an Account. Every registration on the Site assumes prior and unreserved consultation and acceptance by the visitor of all of the present Terms of Use. If the User does not wish to accept these Terms of Use, he must refrain from using the Services.

Access to the Service

Unless otherwise established, the Services are accessible only to corporate bodies or adults.
To access the Service, the User must create – from the Site – an Account protected by a password. The User undertakes to provide true, accurate and complete information and to update it regularly.
The registered User must thereafter identify himself in order to access the Service.
To be able to utilise the Service, the User must have a computer connected to the internet, or a smartphone, also connected to the internet. These costs are borne exclusively by the User.
Withings declines all liability:
- in the event of interruption, bugs or other events rendering the Service unfit for use;
- if the User's computer or smartphone operating system is incompatible with the Service;
- and more generally for any direct or indirect damages, whatever their cause or nature, resulting from use of the Service or the Site.

The Service Provider reserves the right, entirely at its discretion, to temporarily and indefinitely suspend or refuse access to the Service by the User if the latter does not comply with these Terms of Use, or for any other reason. In the case of suspension of the Service, even temporary, these Terms of Use remain applicable.

Account Security

The User is solely responsible for keeping his password confidential and for the actions performed on his Account.
The User must not reveal to anyone information relating to his Account, or use a third party's Account.

Service Content

The Service enables the User:
- to access the Product Interface via certain smartphones;
- to access the Product Interface via the Site;
- to obtain Software to integrate into the Product;
- to obtain software enabling installation of the Product from a computer;
- to access the Site, and, in particular: the showcase, the store, the community spaces, User support, etc.

The User acknowledges that use of the Service or the Products may require the use of other products or hardware or software, and that the User is responsible for that hardware and software.
THE SERVICES AND PRODUCTS TO WHICH THE USER WILL HAVE ACCESS:
- MUST BE USED SOLELY FOR PERSONAL, NON-COMMERCIAL PURPOSES;
- MUST NOT BE SUBJECTED TO CASES OF CRITICAL USE. DETERMINATION OF CRITICALITY IS LEFT TO THE SERVICE PROVIDER'S JUDGMENT.

Changes to the Service or the Product

At its convenience and without prior notice, the Service Provider may modify, add or delete functions of the Service or the Product.

Community services

The User is responsible for information, messages and in general any content distributed via

the community Services, such as the Withings forum or blog.
The User accepts that Withings may eliminate, in whole or in part, any content that it distributes through the interactive services if this content is likely to infringe current laws or regulations or public decency.

Intellectual Property Rights

All texts, photos, logos, trademarks and other elements reproduced on the Site are reserved and protected by copyright, for the entire world.
The User, or a third party, is prohibited from reproducing, representing, distributing, marketing, modifying, utilising or assigning all or part of any of the elements reproduced on the site without the Service Provider's prior consent.
Any unlawful use of all or part of the Site may give rise to criminal prosecution.

Client's Obligations

The User undertakes not to engage in any of the following prohibited activities:
- attempting to use or access the Service via an Account to which he has no right;
- modifying the software supplied, where appropriate, by the Service Provider in order to access the Service, and not to use modified versions of this software and in general not to access it illegally and if not expressly authorised by the Service Provider;
- using the Service for purposes contrary to any current regulations, and not to infringe third-party rights;
- using the Service so as to cause deterioration, interruption or lower performance or to damage its functioning;
- undertaking actions that may, in the Service Provider's judgment, cause an unreasonable or disproportionate increase in the load on our infrastructure;
- interfering with the proper functioning of the Service;
- doing reverse-engineering, decompiling, disassembling or attempting to discover the source code of the Applications.

Changes to the Service's Terms of Use

The Service Provider reserves the right to modify all or part of the Service's Terms of Use without notice.
Use of the Service by the User constitutes full and complete acceptance of any changes made to the present Terms of Use.

Guarantees

The User expressly acknowledges and accepts that the Service Provider:
- does not guarantee that the Services will function without interruption or error;
- cannot guarantee the complete accuracy of the information made available by the Service.

Liability

The User expressly acknowledges and accepts that the Service Provider:
- may temporarily or occasionally interrupt the Service in order to perform maintenance or update operations, without this in any way making the Service Provider liable;

- may in no case be held liable for any damage whatsoever, whether caused directly or indirectly by its services;
- may in no case be held liable for damage to and losses of data suffered by the User. It is therefore up to the User to take all appropriate measures to protect his own data or software from the contamination of his hardware by any viruses circulating on the Internet;
- may in no case be held liable for damages and injury resulting from violation by Users of the rules applying to the community Services (see article 8).

Applicable law

These Terms of Use are governed by French law.
Any dispute resulting from these Terms will fall within the exclusive jurisdiction of the competent French courts.

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AliveCor Privacy Notice

www.alivecor.com/privacy 1/2
Date of last revision: July 19, 2012

We at AliveCor, Inc. (“AliveCor”) respect your concerns about privacy. This Privacy Notice describes the types of personal information we collect through
our mobile app (the “App”) and alivecor.com and alivecorvet.com (the “Sites”), how we use the information, with whom we share it and the choices
available to users of our App and Sites regarding our use of the information. We also describe the measures we take to protect the security of the
information and how users can contact us about our privacy practices.

This Privacy Policy is organized according to the sections below:
Information We Collect
How We Use the Information We Collect
Information We Share
Your Rights And Choices
Data Transfers
How We Protect Personal Information
Links To Other Websites and Applications
Updates To Our Privacy Notice
How To Contact Us

Information We Collect

The types of personal information that users of our Sites and App may submit include:
Contact information (such as name, postal address, email address, and mobile or other telephone number) of individuals such as medical professionals,
human patients and/or their parents or guardians, owners of veterinary patients and other visitors;
username (where applicable) and password;
human patient demographics such as date of birth and gender;
human patient medical data such as medications, ailments; and
payment information (such as payment card number, expiration date, delivery address, and billing address).
Other personal information collected by the App includes human electrocardiography (“ECG”) data, including the ECG measurement itself, average heart
rate and the location on the body where the ECG recording was taken (e.g., hand or chest).
When you visit our Sites or open our emails, we may collect certain information by automated means, such as cookies, web beacons and web server
logs. The information we collect in this manner includes IP address, browser characteristics, device characteristics, operating system version, language
preferences, referring URLs, information on actions taken on our Sites, and dates and times of website visits. A "cookie" is a file that websites send to a
visitor's computer or other Internetconnected
device to uniquely identify the visitor's browser or to store information or settings in the browser. A "web beacon" also known as an Internet tag, pixel tag or clear GIF, links web pages to web servers and their cookies and may be used to transmit information
collected through cookies back to a web server. Through these automated collection methods, we obtain "clickstream data," which is a log of the links
and other content on which a visitor clicks while browsing a website. As the visitor clicks through the website, a record of the action may be collected
and stored. We may link certain data elements we have collected through automated means, such as your browser information, with other information

we have obtained about you to let us know, for example, whether you have opened an email we sent to you. Your browser may tell you how to be
notified when you receive certain types of cookies or how to restrict or disable certain types of cookies. Please note, however, that without cookies you
may not be able to use all of the features of our Sites.
In addition, our App collects information such as the mobile device's phone model and operating system version, as well as the phone's location (with
your consent), local time and time zone.

How We Use The Information We Collect

We may use the information described above to:
Create and manage your account;
provide products and services to you;
deliver and manage customer support;
process your payment;
send you promotional materials or other communications;
communicate with you about, and administer your participation in, special events, programs, offers, surveys and market research;
respond to your inquiries;
perform data analyses (including anonymization and aggregation of personal information);
operate, evaluate and improve our business (including developing new products and services; enhancing and improving our services; managing our
communications; analyzing our products; and performing accounting, auditing and other internal functions);
protect against, identify and prevent fraud and other unlawful activity, claims and other liabilities; and comply with and enforce applicable legal requirements, relevant industry standards and our policies.
We also may use the information in other ways for which we provide specific notice at the time of collection.
In addition, we use information collected through cookies, web beacons, web server logs and other automated means for purposes such as (i)

customizing our users' visits to our websites, (ii) delivering content tailored to our users' interests and the manner in which our users browse our
websites, and (iii) managing our websites and other aspects of our business. To the extent required by applicable law, we will obtain your consent before
collecting information by automated means using cookies or similar automated means.
We may use thirdparty
web analytics services on our Sites, such as those of Google Analytics. The analytics providers that administer these services use
technologies such as cookies, web server logs and web beacons to help us analyze how visitors use the Sites and improve the overall experience of the
Sites. The information collected through these means (including IP address) is disclosed to these analytics providers, who use the information to
evaluate use of the Sites. To learn more about Google Analytics and how to opt out, please
visit http://www.google.com/analytics/learn/privacy.html.

Information We Share

We do not sell or otherwise disclose personal information we collect about you, except as described in this Privacy Notice. With consent, we may share
information relating to patients (as well as veterinary patients' owners and human patients' parents or guardians) with the patients' medical
professionals, whose use, disclosure and other handling of this information is subject to their own privacy policies and practices and not this Privacy

Notice. We may share your personal information among our subsidiaries and affiliates for the purposes described in this Privacy Notice. We also may share personal information with service providers who perform services on our behalf based on our instructions. We do not authorize these service providers to use or disclose the information except as necessary to perform services on our behalf or comply with legal requirements. Examples of these service providers include entities that analyze ECG data to diagnose cardiac conditions, process credit card payments, fulfill orders and provide web hosting services.

In addition, we may disclose information about you (i) if we are required to do so by law or legal process, (ii) to law enforcement authorities or other government officials, and (iii) when we believe disclosure is necessary or appropriate to prevent physical harm or financial loss, or in connection with an investigation of suspected or actual fraudulent or illegal activity.

We also reserve the right to transfer personal information we have about you in the event we sell or transfer all or a portion of our business or assets (including in the event of a reorganization, dissolution or liquidation). Should such a sale or transfer occur, we will use reasonable efforts to direct the transferee to use personal information you have provided to us in a manner that is consistent with our Privacy Notice. Following such a sale or transfer, you may contact the entity to which we transferred your personal information with any inquiries concerning the processing of that information.

Your Rights and Choices

We offer you certain choices in connection with the personal information we collect from you, such as how we use the information and how we communicate with you. To update your preferences, ask us to remove your information from our mailing lists or submit a request, please contact us as indicated in the “How to Contact Us” section of this Privacy Notice. Users with online accounts may be able to update or delete certain personal information on our Sites. To the extent provided by the law of your jurisdiction, you may request access to the personal information we maintain about you or request that we correct, amend, delete or block the information by contacting us as indicated below. Where provided by law, you may withdraw any consent you previously provided to us or object at any time on legitimate grounds to the processing of your personal information, and we will apply your preferences going forward.

Data Transfers

We may transfer the personal information we collect about you to countries other than the country in which the information originally was collected. Those countries may not have the same data protection laws as the country in which you initially provided the information. When we transfer your information to other countries, we will protect that information as described in this Privacy Notice.

How We Protect Personal Information

We maintain administrative, technical and physical safeguards designed to protect the personal information you provide against accidental, unlawful or unauthorized destruction, loss, alteration, access, disclosure or use.

Links To Other Websites and Applications

Our Sites and App may provide links to other websites and applications for your convenience and information. These websites and applications may operate independently from us. Linked sites and applications may have their own privacy notices or policies, which we strongly suggest you review. To the extent any linked websites or applications are not owned or controlled by us, we are not responsible for the sites’ or applications’ content, any use of

the sites or applications, or the privacy practices of the sites or applications.

Updates To Our Privacy Notice

This Privacy Notice may be updated periodically and without prior notice to you to reflect changes in our personal information practices. We will post a prominent notice on our Sites to notify you of any significant changes to our Privacy Notice and indicate at the top of the notice when it was most recently updated.

How To Contact Us

If you have any questions or comments about this Privacy Notice, or if you would like us to update information we have about you or your preferences, please contact us by email at privacy@alivecor.com. You also may write to: 30 Maiden Lane, 6th Floor, San Francisco, CA 94108.

ALIVECOR, INC. TERMS OF SERVICE

THE AliveECG MOBILE APPLICATION AND WEB SERVICE (hereafter, the "Application") IS AVAILABLE FOR PRESCRIPTION USE ONLY IN THE UNITED STATES OF AMERICA (USA) AND TO USERS IN THE MEMBER STATES OF THE EUROPEAN UNION. THE APPLICATION IS INTENDED TO ONLY RECORD, DISPLAY, STORE AND TRANSMIT ELECTROCARDIOGRAMS (ECG Data). THE USER OF THE APPLICATION IS RESPONSIBLE FOR THE ECG DATA RECORDED AND STORED BY THE APPLICATION. THE APPLICATION IS NOT INTENDED TO DIAGNOSE ANY HEART CONDITION OR ALERT HEALTHCARE PROFESSIONALS OR PATIENTS TO POTENTIALLY SERIOUS HEART CONDITIONS OR ABNORMAL ARRHYTHMIAS. ALIVECOR, INC. (AliveCor) DOES NOT REVIEW, MONITOR, EVALUATE OR ANALYZE ANY INFORMATION GENERATED FROM THE APPLICATION. By clicking the "I AGREE" button that follows these Terms and Conditions or by otherwise accessing or using the Application, you ("You") understand and agree to the above description of the Application and agree as follows:

1. REGISTRATION; TERM OF REGISTRATION

1.1. Registration through the Application

You must be a registered user with AliveCor, Inc. ("AliveCor") in order to use the Application. You may register through the Application or through the AliveCor website located at http://www.alivecor.com ("Website"). By submitting the information requested in the Application's online registration form, You may access and use the Application and Website to view certain data pertaining to You as made available by AliveCor. You may not access or use the Application or Website for any other purpose.

1.2. Term of Your Registration

The term of Your registration will commence as of the date You complete Your online registration form ("Registration Date") and, unless earlier terminated in accordance with these Terms and Conditions, will continue in perpetuity ("Term"). Notwithstanding the foregoing, Your registration may automatically expire following any period of inactivity associated with Your account in excess of twelve (12) consecutive months.

1.3. Notices

All notices from AliveCor intended for receipt by You shall be deemed delivered and effective when sent to the email address provided by You during the registration process or when posted to and made available to You on Application or Website (in either case, "Notice"). If You change the email address provided in connection with Your registration to access and use the Application, You must update Your address in accordance with the procedures set forth on the Website.

2. MODIFICATIONS TO THE APPLICATION / TERMS AND CONDITIONS

2.1. Modifications to the Application / Terms and Conditions

You acknowledge and agree that AliveCor may, in its sole discretion, modify the Application and these Terms and Conditions (including any instructions, policies or guidelines referenced herein) at any time and in any manner. Upon modification of these Terms and Conditions, AliveCor will notify You for Your consent. All such modifications shall be binding upon You when made. You may not amend or modify the Application, Website or these Terms and Conditions under any circumstances.

3. 3. REPRESENTATIONS, COVENANTS AND WARRANTIES

3.1. Representations, Covenants and Warranties of Registrant

You represent, covenant and warrant to AliveCor that (1) You are a licensed healthcare professional in the USA, or You have been prescribed the Application by a licensed healthcare professional in the USA, or you are a resident of a Member State in the European Union; (2) will use the Application as intended; (3) these Terms and Conditions have been executed and delivered by You and constitute a valid and binding agreement with You, enforceable against You in accordance with their terms; (4) You will not access or use the Application or Website except as expressly permitted by these Terms and Conditions and any additional instructions, guidelines or policies issued by AliveCor, including those posted in the Application or on the Website; (5) You will access and use the Application and Website in full compliance with applicable Law (as defined in Section 4.1); and (6) all of the information, data and other materials provided by You in support of Your online registration are accurate and truthful in all respects.

3.2. Disclaimer

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THESE TERMS AND CONDITIONS, ALIVECOR MAKES NO REPRESENTATIONS, COVENANTS OR WARRANTIES AND OFFERS NO OTHER CONDITIONS, EXPRESS OR IMPLIED, REGARDING ANY MATTER, INCLUDING (1) THE MERCHANTABILITY, SUITABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, NON-INFRINGEMENT OR RESULTS TO BE DERIVED FROM THE USE OF THE APPLICATION, WEBSITE OR ANY DATA SERVICE, SOFTWARE, HARDWARE, DELIVERABLE, WORK PRODUCT OR OTHER MATERIALS RELATED TO THE APPLICATION OR WEBSITE, OR THE AVAILABILITY OF ANY OF THE FOREGOING; OR (2) WHETHER THE INFORMATION AVAILABLE ON OR TRANSMITTED BY THE APPLICATION OR WEBSITE IS TRUE, COMPLETE OR ACCURATE. YOU SPECIFICALLY ACKNOWLEDGE AND AGREE THAT ALIVECOR IS NOT RESPONSIBLE FOR ANY HEALTHCARE OR RELATED DECISIONS MADE BY YOU OR YOUR HEALTHCARE PROFESSIONAL BASED UPON DATA COLLECTED, TRANSMITTED OR DISPLAYED BY OR ON THE APPLICATION OR WEBSITE, WHETHER SUCH DATA IS ACCURATE OR INACCURATE. FURTHER, ALIVECOR DOES NOT REPRESENT, COVENANT OR WARRANT THAT ACCESS TO OR SERVICES PROVIDED BY THE APPLICATION OR WEBSITE WILL BE UNINTERRUPTED OR ERROR-FREE. YOU ACKNOWLEDGE AND AGREE THAT THERE ARE RISKS INHERENT TO TRANSMITTING INFORMATION OVER AND STORING INFORMATION ON THE INTERNET AND THAT ALIVECOR IS NOT RESPONSIBLE FOR ANY LOSSES OF YOUR DATA, CONFIDENTIALITY OR PRIVACY IN CONNECTION THEREWITH.

4. COMPLIANCE

4.1. Generally

You shall use the Application and Website in strict compliance with (1) these Terms and Conditions; (2) any additional instructions, guidelines or policies issued by AliveCor, including those posted within the Application or on the Website; and (3) all applicable laws, rules and regulations (collectively, "Laws").

5. CONTRACTORS

5.1. Use of Contractors

AliveCor may engage any third party (including AliveCor's affiliates) to perform, or support the performance of, all or any portion of the Application or the Website. Any engagement

with any third party will be conducted in accordance with the AliveCor Privacy Notice described in Section 7.1.

6. INTELLECTUAL PROPERTY RIGHTS; RESTRICTIONS ON USE

6.1. Ownership of the Application and Related Data

As between AliveCor and You (collectively, "Parties"), AliveCor owns and will retain ownership of all rights, title and interest in and to the Application and the Website, including (1) all content displayed on the Application or the Website, to the extent such content is developed by AliveCor or its third party licensors, including any derivative works of the Application or Website and any such content; (2) any data presented on or by the Application or Website or otherwise stored by AliveCor and its third party providers, except for personal information that You submit to AliveCor during the registration process or through Your use of the online forms on the Website or Application (which shall be owned by You); and (3) any intellectual property or other proprietary rights comprising any of the foregoing (collectively, "AliveCor IP"). Neither these Terms and Conditions nor any disclosure made hereunder grant any license to You under any AliveCor IP.

6.2. Use of the Application

You may use the Application and the Website, including any data presented on or by the Application or Website for You, or otherwise hosted or stored by AliveCor for You, only on Your own behalf and for lawful and appropriate purposes. You shall not use the Application, the Website or any of the data presented on or by the Application or Website, or otherwise hosted or stored by AliveCor, for any commercial purpose other than as expressly permitted herein. You will notify AliveCor immediately upon any suspected unauthorized use of the Application or Website, whether by You or a third party, or any suspected loss of or suspected unauthorized access to passwords or other log-in information used by You to access the Application or Website ("Login Credentials"). You shall be solely responsible for maintaining the confidence and security of any Login Credentials, and AliveCor shall bear no liability or other responsibility associated therewith.

7. PRIVACY NOTICE

7.1. Privacy Notice

You explicitly consent to the collection, hosting, use, disclosure and other processing or handling of information as described in the AliveCor Privacy Notice located at http://alivecor.com/privacy, as such notice may be amended by AliveCor in its sole discretion from time to time. Upon modification of the Privacy Notice, AliveCor will notify You for Your consent.

8. SUSPENSION AND TERMINATION

8.1. Suspension

AliveCor may suspend or limit Your access to the Application or the Website if AliveCor, in its sole discretion, suspects that You are in violation of, or reasonably likely to be in violation of, these Terms and Conditions or any additional instructions, guidelines or policies issued by AliveCor, including those posted in the Application or on the Website.

8.2. Non-Renewal

You may cancel Your registration at any time in accordance with the procedures described on the Website.

8.3. Termination by AliveCor

AliveCor may terminate Your registration, including Your right to access and use the Website or the Application, in whole or in part, as follows:

For Cause. Immediately (1) in order to comply with applicable Law or instructions from any governmental agency or authority; (2) if AliveCor, in its sole discretion, suspects that You are using the Application or Website in a manner not permitted by these Terms and Conditions; or (3) upon any breach of these Terms and Conditions by You.

For Convenience. For convenience, upon notice by AliveCor to You.

8.4. Effect of Termination

Upon the expiration or earlier termination of Your registration or rights to use the Application or Website, for any reason (i) You will no longer be authorized to access or use the Application or Website or otherwise use any of the features or services offered by or through the Application or Website; (ii) AliveCor may delete any data associated with You or Your account; and (iii) all rights and obligations of the Parties under these Terms and Conditions shall expire, except those rights and obligations under those sections specifically designated in Section 8.5.

8.5. Survival of Selected Provisions

Notwithstanding the expiration or earlier termination of Your registration or rights to use the Application or Website, the following sections of the Terms and Conditions shall survive any such expiration or termination: Sections 3.2, 6.1, 8.4, 9, 10, 11 and 12.

9. LIABILITY

9.1. Limitation of Liability

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE ALIVECOR GROUP (AS DEFINED IN SECTION 10.1) SHALL NOT BE LIABLE TO YOU FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RESULTING FROM YOUR USE OF THE APPLICATION OR WEBSITE, OR BASED UPON ANY BREACH OF ANY EXPRESS OR IMPLIED WARRANTY, BREACH OF CONTRACT (INCLUDING THESE TERMS AND CONDITIONS AND ANY ADDITIONAL INSTRUCTIONS, GUIDELINES OR POLICIES ISSUED BY ALIVECOR, INCLUDING THOSE POSTED IN THE APPLICATION OR ON THE WEBSITE), NEGLIGENCE, TORT OR ANY OTHER LEGAL THEORY (COLLECTIVELY, THE "EXCLUDED DAMAGES"). FOR THE AVOIDANCE OF DOUBT, THE EXCLUDED DAMAGES ALSO INCLUDE WITHOUT LIMITATION, LOSS OF SAVINGS OR REVENUE; LOSS OF PROFIT; LOSS OF USE; LOSS OF LIFE OR HEALTH, THE CLAIMS OF THIRD PARTIES; AND ANY COST OF ANY SUBSTITUTE EQUIPMENT OR SERVICES. IF ALIVECOR CANNOT LAWFULLY DISCLAIM LIABILITY FOR ANY OF THE FOREGOING DAMAGES, THEN ALIVECOR GROUP'S MAXIMUM LIABILITY TO YOU IS LIMITED TO THE PURCHASE PRICE PAID BY YOU TO ALIVECOR FOR THE APPLICATION. THESE LIMITATIONS APPLY EVEN IF ANY OTHER REMEDIES AVAILABLE TO YOU FAIL OF THEIR ESSENTIAL PURPOSE. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

9.2. Remedies

At its option, any member of the AliveCor Group may seek all remedies available to it under law and in equity, including injunctive relief in the form of specific performance to enforce

these Terms and Conditions, including any additional instructions, guidelines or policies issued by AliveCor, including those posted in the Application or on the Website, and/or actions for damages.

9.3. Claims

No action arising out of, in connection with, or relating to these Terms and Conditions or the subject of these Terms and Conditions shall be brought by You more than one (1) year after the accrual of the cause of action. This period shall not be extended for any reason, except by the written consent of both parties. All statutes or provisions of law which would toll or otherwise affect the running of the period of limitation are hereby waived, and no such statute or provision of law shall operate to extend the period limited in this paragraph.

10. INDEMNITIES

10.1. Indemnity by You

You will indemnify and hold harmless AliveCor, its affiliates and their respective current, future or former officers, directors, partners, equity holders, employees, agents, contractors, and their successor or assigns (collectively, the "AliveCor Group") on demand, from and against any and all fines, penalties, liabilities, losses and other damages of any kind whatsoever (including attorneys' and experts' fees), incurred by any of the members of the AliveCor Group, and, if directed by AliveCor, shall defend the AliveCor Group against (1) all claims that any information, data or other materials provided by You in connection with your use of the Website or the Application (including Your application for registration to access and use the Application or Website) or these Terms and Conditions, or use thereof by any member of the AliveCor Group, infringes, misappropriates or otherwise violates any patent, trademark, copyright, trade secret or other intellectual property or proprietary right of a third party; (2) all claims arising from fraud committed by, or the intentional misconduct, criminal acts or gross negligence of, You; and (3) all claims otherwise arising due to a failure by You to comply with any term or condition of these Terms and Conditions, including any additional instructions, guidelines or policies issued by AliveCor, including those posted in the Application or on the Website.

11. DISPUTE RESOLUTION

11.1. Disputes

If a dispute arises under these Terms and Conditions between You and any member of the AliveCor Group, such dispute shall be resolved, at the filing party's election, in either a small claims court or by final and binding arbitration administered by the National Arbitration Forum or the American Arbitration Association, under their rules for consumer arbitrations. All disputes in arbitration will be handled solely between the named parties, and not on any representative or class basis. ACCORDINGLY, YOU ACKNOWLEDGE THAT IT MAY NOT HAVE ACCESS TO A COURT (OTHER THAN A SMALL CLAIMS COURT) OR JURY. Notwithstanding any other provision of these Terms and Conditions, any member of the AliveCor Group may resort to court action for injunctive relief at any time if, in its good faith belief, the dispute resolution procedures described in this Section 11.1 would permit or cause irreparable injury to such member of the AliveCor Group or any third party claiming against a member of the AliveCor Group, due to delay arising out of such dispute resolution procedures.

11.2.Governing Law

All rights and obligations of You or the AliveCor Group relating to these Terms and Conditions, including any additional instructions, guidelines or policies issued by AliveCor, including those posted in the Application or on the Website, shall be governed by and construed in accordance with the Law of the United States of America, State of New York without giving effect to any choice-of-law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the Laws of any other jurisdiction.

12.GENERAL

12.1.Entire Agreement, Amendments and Modifications

These Terms and Conditions any additional instructions, guidelines or policies issued by AliveCor, including those posted in the Application or on the Website constitute the entire agreement of the Parties with regard to Your use of the Application and the Website, and all matters addressed herein, and all prior agreements, letters, proposals, discussions and other documents regarding the Application or the Website and the matters herein are superseded and merged into these Terms and Conditions.

12.2.Force Majeure

AliveCor will be excused from performance under these Terms and Conditions for any period that it is prevented from or delayed in performing any obligations pursuant to these Terms and Conditions, in whole or in part, as a result of a Force Majeure Event. For purposes of this Section 12.2, "Force Majeure Event" means an event or series of events caused by or resulting from any of the following- (1) weather conditions or other elements of nature or acts of God; (2) acts of war, acts of terrorism, insurrection, riots, civil disorders or rebellion; (3) quarantines or embargoes, (4) labor strikes; (4) telecommunications, network, computer, server or Internet downtime; (5) unauthorized access to AliveCor's information technology systems by third parties; or (6) other causes beyond the reasonable control of AliveCor.

12.3.Severability

If any provision of these Terms and Conditions shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby, and such provision shall be deemed to be restated to reflect the Parties' original intentions as nearly as possible in accordance with applicable Law(s).

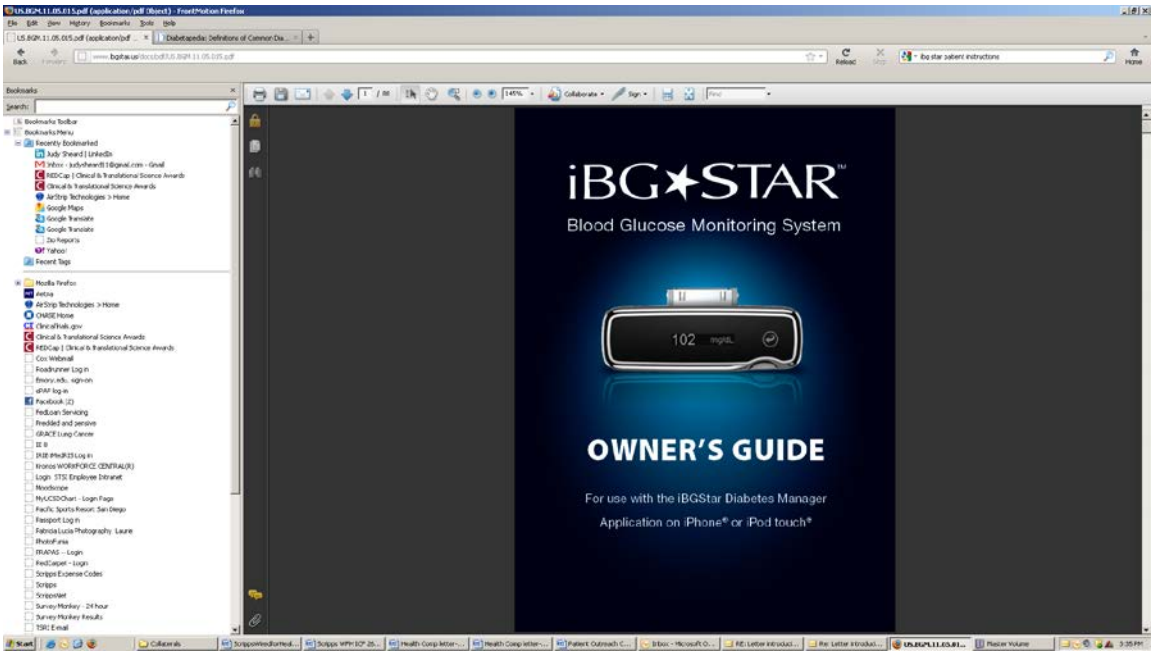
12.4.Assignment

You may not assign these Terms and Condition (or any rights, benefits or obligations hereunder) by operation of law or otherwise without the prior written consent of AliveCor, which may be withheld at AliveCor's sole discretion. Any attempted assignment by You that does not comply with the terms of this Section 12.4 shall be null and void. AliveCor may assign these Terms and Conditions, in whole or in part, to any third party in its sole discretion.

Appendix 12: iBG Star Owner's Guide

Patients will receive a hard copy and web link for the Owner's Guide.

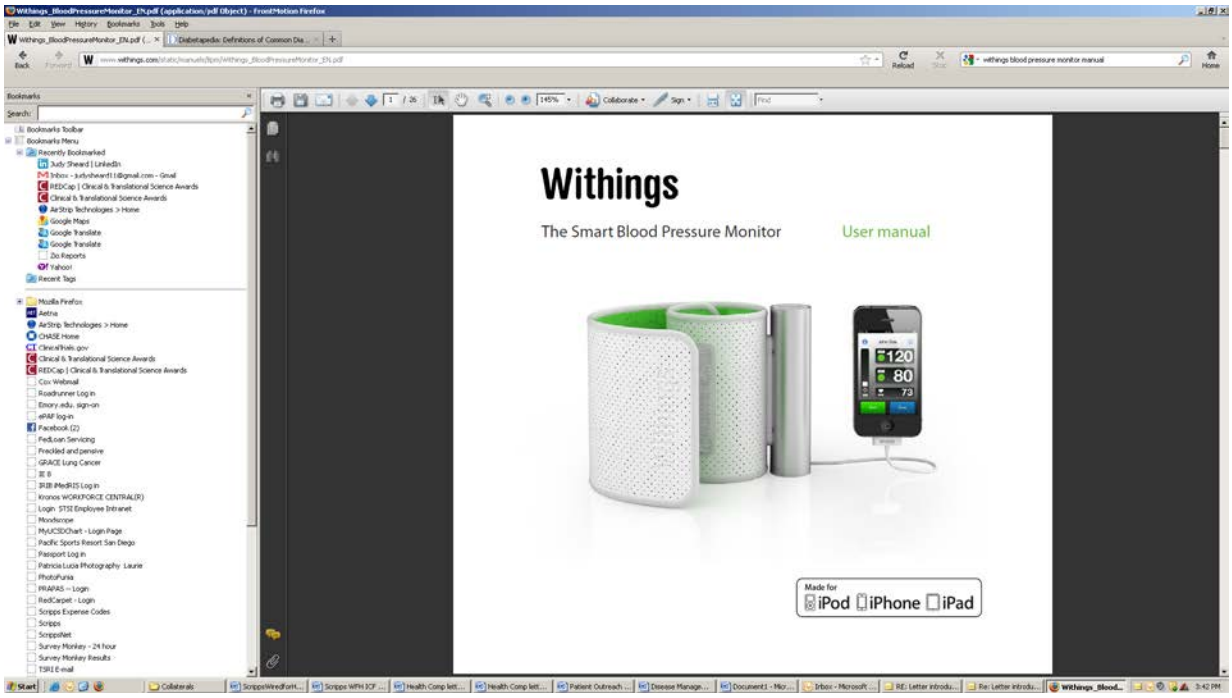
[iBG Star Blood Glucose Monitoring System Owner's Guide]



Appendix 13: Withings Blood Pressure Monitor User Manual

Patients will receive a hard copy and web link for the User Manual.

Withings Blood Pressure Monitor User Manual



Appendix 14: Instructions for AliveCor ECG

Patients will receive a hard copy of the AliveCor Quick Start Guide.

QUICK START GUIDE FOR DEMONSTRATION PURPOSES

PRODUCT DESCRIPTION

The AliveCor™ Heart Monitor is a mobile, clinical-quality electrocardiogram (ECG) recorder for use by both physicians and patients. The duration of the ECG recording is customizable from 30 seconds to continuous. The software application can store thousands of recordings on your iPhone 4 or 4S, and these recordings are also accessible to you on the AliveCor, Inc. server. The device consists of two components:

- The Heart Monitor, which snaps onto the iPhone and contains sensors and electronics used to collect ECG rhythms and transmit them to the iPhone.
- The AliveECG mobile application (AliveECG App) used to collect, view, save, and wirelessly transmit ECG recordings to the AliveCor server.

The Heart Monitor enables the physician or patient to:

- Collect and view single-channel ECG rhythms using the iPhone.
- Store ECG recordings on the iPhone.
- Wirelessly transmit ECG recordings to the AliveCor server.
- Access ECG recordings stored on the AliveCor server from anywhere in the world, and print the recording or save it to a hard drive.

DOWNLOAD THE ALIVEECG APP

Please contact Jessica Dinsdale (jessica@alivecor.com / 860-604-8754), Senior Clinical Engineer at AliveCor, to receive instructions on how to download the app to your iPhone 4 or 4S. As the device is not cleared by the FDA for sale in the United States, we are unable to provide an app in the App Store for download, therefore the app will need to be downloaded directly.

SET UP AN ALIVECOR ACCOUNT

You will use your AliveCor account to access, print, and save your ECG recordings stored on the AliveCor server. Follow the instructions presented when you open the AliveECG App for the first time. You can go back later and change your information if necessary.

RECORD ECG RHYTHMS USING THE HEART MONITOR

Before taking your first recording, read these instructions carefully and make sure you observe the following instructions each time you take a recording.

- Make sure the Heart Monitor is properly attached to your iPhone.
- Disconnect headphones, charger cables, or any other connected devices
- Clean the two electrodes with an alcohol-based sanitizer.
- Using your iPhone, launch the AliveECG App.
- Hold the system using two hands; the left hand should contact the electrode closer to the top of the iPhone, and the right hand should contact the electrode closer to the bottom of the iPhone. Recording will begin automatically when both electrodes make contact with skin. Alternatively, the Heart Monitor can be placed on the patient's chest to obtain a recording.

The ECG rhythms will appear best when the Heart Monitor is held steady. It may be helpful to rest your arms on a flat surface to increase stability.

If you remove contact before 10 seconds of recording has occurred, the ECG will not be saved, and you will not be able to review it.

ACCESS AND VIEW PREVIOUSLY RECORDED ECG RHYTHMS

You can view previously recorded ECGs within the AliveECG App or by logging into your account at www.alivecor.com.

Protected health information (ECGs) and personally identifiable information are encrypted in transit and at rest. ECGs are stored on fully secure, HIPAA-compliant servers and data is only accessible via your user name and password.

INDICATIONS FOR USE

The Heart Monitor is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms. There are no known contraindications for the Heart Monitor, although care should be taken when using the device on infants weighing less than 10kg. AliveCor does not recommend using on patients with a cardiac pacemaker or other implanted electronic devices.

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician.

INTENDED USER

The device is intended to be used by licensed medical professionals or by a patient under the care and supervision of a physician.

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GENERAL SAFETY PRECAUTIONS

- The device should not be used in conjunction with water, or in a wet environment.
- Do not sterilize this unit with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Disperse any static electricity from your body before using the unit.
- Do not take recordings in a moving vehicle.
- Do not expose the unit to strong shocks or vibrations.
- Do not disassemble, repair, or modify the unit.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use for any purpose other than obtaining an electrocardiogram.
- Do not take recordings in a location where the unit will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Do not use this unit in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- If the portion of the body where the electrode is applied has too much body fat, body hair or very dry skin, a successful recording may not be possible.
- Do not place this unit onto metal surfaces. This will deplete the battery.

STORAGE, HANDLING AND MAINTENANCE

Do not store the unit in:

- Locations exposed to direct sunlight
- Locations subject to high temperatures and high humidity
- Wet or damp locations where water may get on the unit
- Dusty locations
- Near fires or open flames
- Locations exposed to strong vibration
- Locations exposed to strong electromagnetic fields.

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using an alcohol-based sanitizer before each use.

WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions.
- This device measures heart rate and heart rhythm only.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Patients should always consult their physician if they notice changes in their health, regardless of recording results.
- Do not use this device with a defibrillator.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

REMOVE THE HEART MONITOR FROM YOUR IPHONE

To remove the device from your iPhone, press gently on the iPhone through the camera hole while holding the device from the edge. The iPhone should partially pop out of the device and be easily removed.

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Appendix 15:

Healthy Circles Sample iPhone Display

Appendix 16:

Text for Study Landing Page (http://wiredforhealth.healthcomp.com)

Wired for Health

The Wired for Health Study is a randomized clinical study that will evaluate the impact of remote wireless monitoring for patients with diabetes, hypertension, and arrhythmias.

This study will test whether wireless monitoring can reduce health care costs and increase health self-management for patients with chronic health conditions.

About the Study

A total of 100 individuals in the Monitoring group will be provided with i-Phones and the wireless device(s) most appropriate for monitoring their particular medical diagnosis. Patients will use the devices for a period of six months. The study will look at the patients' health care insurance claims and compare them to the insurance claims of the 100-person Control group.

For the study, Health Comp is working with these companies:

Scripps Health [http://www.scripps.org/]

Scripps Translational Science Institute [http://www.stsiweb.org/]

Qualcomm Life [http://www.qualcommlife.com/]

HealthyCircles [http://www.healthycircles.com/]

Accenture Technology Labs [http://www.accenture.com]

Frequently Asked Questions

Who is selected to participate?
A person is potentially eligible to participate in this study if he or she has diabetes, hypertension, or a cardiac arrhythmia.

Who is Health Comp?
Health Comp is responsible for processing all health care insurance claims for employees and dependents of Scripps Health. Health Comp also administers health and wellness

programs to Scripps Employees and dependents and will the primary point of contact for study participants.

Why are so many different companies involved in this study?
This study has several different components, including i-Phones, three wireless health monitoring devices, iPhone apps, and a health tracking and education portal. Each company involved in the study is responsible for a different component.

Will participants interact with all of these companies?
No, only Health Comp clinical staff and Scripps Translational Science Institute research coordinators will work with the study participants.

Are patients' personal physicians involved in the study?
Participants' physicians are not part of this study and will not receive testing results unless a participant provides it to him or her. Health Comp clinical staff and researchers at the Scripps Translational Science Institute will receive and house participants' results, but only for research purposes.

Will participants benefit from participating in this research?
Upon completion of the study, participants will receive a $20 gift card, in addition to 10 Scripps Health Wellness points. If a Scripps employee earns 15 Wellness points in a calendar year (through participating in other Scripps Wellness activities), they are eligible for a reduction in health insurance costs.

What will happen to participants if they agree to be in the study?
If a participant agrees to be in the study, he or she will be assigned to one of two groups. Participants in the Monitoring Group will be given a wireless device, trained on how to use it, and will be asked to self-monitor vitals using the device(s) for 6 months. Participants in the Control Group will not receive a monitoring device or be asked to self-monitor vitals.

Will participants' employer or health insurance company be able to find out their results?
Participants' research results will be used for research purposes only. They will not become part of Scripps employment, medical, or insurance records.

IMPORTANT: BY USING YOUR iPHONE, YOU ARE AGREEING TO BE BOUND BY THE FOLLOWING APPLE AND THIRD PARTY TERMS:

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B. NOTICES FROM APPLE
C. GOOGLE MAPS TERMS AND CONDITIONS
D. YOUTUBE TERMS AND CONDITIONS

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1. General. The software (including Boot ROM code and other embedded software), documentation, interfaces, content, fonts and any data that came with your iPhone ("Original iPhone Software"), as may be updated or replaced by feature enhancements, software updates or system restore software provided by Apple ("iPhone Software Updates"), whether in read only memory, on any other media or in any other form (the Original iPhone Software and iPhone Software Updates are collectively referred to as the "iPhone Software") are licensed, not sold, to you by Apple Inc. ("Apple") for use only under the terms of this License. Apple and its licensors retain ownership of the iPhone Software itself and reserve all rights not expressly granted to you.

Apple, at its discretion, may make available future updates to the operating system software for your iPhone. Updates, if any, may not necessarily include all existing software features, or new features that Apple releases for newer iPhone models.

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4. Consent to Use of Data.
(a) Anonymous Diagnostic and Usage Data. You agree that Apple and its subsidiaries and agents may collect, maintain, process and use diagnostic, technical, usage and related information, including but not limited to information about your iPhone, computer, system and application software, and peripherals, that is gathered periodically to facilitate the provision of software updates, product support and other services to you (if any) related to the iPhone Software, and to verify compliance with the terms of this License. Apple may use this information, as long as it is collected anonymously in a form that does not personally identify you, to improve our products or to provide services or technologies to you.
(b) Location Data. Apple and its partners and licensees may provide certain services through your iPhone that rely upon location information. To provide and improve these services, where available, Apple and its partners and licensees may transmit, collect, maintain, process and use your location data, including the real-time geographic location of your iPhone, and location search queries. The location data and queries collected by Apple are collected in a form that does not personally identify you and may be used by Apple and its partners and licensees to provide and improve location-based products and services. **By using any location-based services on your iPhone, you agree and consent to Apple's and its partners' and licensees' transmission, collection, maintenance, processing and use of your location data and queries to provide and improve such products and services.** You may withdraw this consent at any time by going to the Location Services setting on your iPhone and either turning off the global Location Services setting or turning off the individual location settings of each location-aware application on your iPhone. Not using these location features will not impact the non location-based functionality of your iPhone. When using third party applications or services on the iPhone that use or provide location data, you are subject to and should review such third party's terms and privacy policy on use of location data by such third party applications or services.
(c) Video Calls. The FaceTime video call feature of the iPhone Software ("FaceTime") requires Internet access and may not be available in all countries or regions. Your use of FaceTime is subject to your compliance with Section 2(e) above and you understand that your iPhone's telephone number will be displayed to the other party on the FaceTime video call, even if you have a blocked number. **By using the iPhone Software, you agree that Apple may use and maintain your iPhone's telephone number as a unique account identifier for the purpose of providing**

and improving the FaceTime feature. You may turn off the FaceTime feature by going to the FaceTime Setting on your iPhone and turning it off or by going to the Restrictions setting on your iPhone and enabling the FaceTime restriction.

(d) Interest-Based Advertising. Apple may provide mobile, interest-based advertising to you. If you do not want to receive relevant ads on your iPhone, you can opt out by going to this link on your iPhone: http://oo.apple.com. If you opt out, you will continue to receive the same number of mobile ads, but they may be less relevant because they will not be based on your interests. You may still see ads related to the content on a web page or in an application or based on other non-personal information. This opt-out applies only to Apple advertising services and does not affect interest-based advertising from other advertising networks.

At all times your information will be treated in accordance with Apple's Privacy Policy, which is incorporated by reference into this License and can be viewed at: www.apple.com/legal/privacy/.

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(a) The iPhone Software contains MPEG-4 video encoding and/or decoding functionality. The iPhone Software is licensed under the MPEG-4 Visual Patent Portfolio License for the personal and non-commercial use of a consumer for (i) encoding video in compliance with the MPEG-4 Visual Standard ("MPEG-4 Video") and/or (ii) decoding MPEG-4 video that was encoded by a consumer engaged in a personal and non-commercial activity and/or was obtained from a video provider licensed by MPEG LA to provide MPEG-4 video. No license is granted or shall be implied for any other use. Additional information including that relating to promotional, internal and commercial uses and licensing may be obtained from MPEG LA, LLC. See http://www.mpegla.com.

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September 2007

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YouTube may, in its sole discretion, modify or revise these Terms of Service and policies at any time, and you agree to be bound by such modifications or revisions. Nothing in this Agreement
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A. These Terms of Service apply to all users of the YouTube Website, including users who are also contributors of video content, information, and other materials or services on the
Website. The YouTube Website includes all aspects of YouTube, including but not limited to all products, software and services offered via the website such as the YouTube channels,
the YouTube "Embeddable Player," the YouTube "Uploader" and other applications.

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expressly relieve YouTube from any and all liability arising from your use of any third-party website.

C. Accordingly, we encourage you to be aware when you leave the YouTube Website and to read the terms and conditions and privacy policy of each other website
that you visit.

3. YouTube Accounts

A. In order to access some features of the Website, you will have to create a YouTube account. You may never use another's account without permission. When creating your
account, you must provide accurate and complete information. You are solely responsible for the activity that occurs on your account, and you must keep your account password
secure. You must notify YouTube immediately of any breach of security or unauthorized use of your account.

B. Although YouTube will not be liable for your losses caused by any unauthorized use of your account, you may be liable for the losses of YouTube or others due to such
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YouTube hereby grants you permission to access and use the Website as set forth in these Terms of Service, provided that:

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B. You agree not to alter or modify any part of the Website, including but not limited to YouTube's Embeddable Player or any of its related technologies.

C. You agree not to access User Submissions (defined below) or YouTube Content through any technology or means other than the video playback pages of the Website itself, the YouTube
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F. (For more information about what constitutes a prohibited commercial use, see our FAQ.)
G. If you use the YouTube Embeddable Player on your website, you must include a prominent link back to the YouTube website on the pages containing the Embeddable Player and you may
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K. YouTube reserves the right to discontinue any aspect of the YouTube Website at any time.

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B. You shall be solely responsible for your own User Submissions and the consequences of posting or publishing them. In connection with User Submissions, you affirm, represent, and/or warrant that: you own or have the necessary licenses, rights, consents, and permissions to use and authorize YouTube to use all patent, trademark, trade secret, copyright or other proprietary rights in and to any and all User Submissions to enable inclusion and use of the User Submissions in the manner contemplated by the Website and these Terms of Service.
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E. You further agree that you will not, in connection with User Submissions, submit material that is contrary to the YouTube Community Guidelines, found at http://www.youtube.com/t/community_guidelines, which may be updated from time to time, or contrary to applicable local, national, and international laws and regulations.

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B. YouTube reserves the right to decide whether Content or a User Submission is appropriate and complies with these Terms of Service for violations other than copyright infringement, such as, but not limited to, pornography, obscene or defamatory material, or excessive length. YouTube may remove such User Submissions and/or terminate a User's access for uploading such material in violation of these Terms of Service at any time, without prior notice and at its sole discretion.

8. Digital Millennium Copyright Act

A. If you are a copyright owner or an agent thereof and believe that any User Submission or other content infringes upon your copyrights, you may submit a notification pursuant to the Digital Millennium Copyright Act ("DMCA") by providing our Copyright Agent with the following information in writing (see 17 U.S.C 512(c)(3) for further detail):

- A physical or electronic signature of a person authorized to act on behalf of the owner of an exclusive right that is allegedly infringed;
- Identification of the copyrighted work claimed to have been infringed, or, if multiple copyrighted works at a single online site are covered by a single notification, a representative list of such works at that site;
- Identification of the material that is claimed to be infringing or to be the subject of infringing activity and that is to be removed or access to which is to be disabled and information reasonably sufficient to permit the service provider to locate the material;
- Information reasonably sufficient to permit the service provider to contact you, such as an address, telephone number, and, if available, an electronic mail;
- A statement that you have a good faith belief that use of the material in the manner complained of is not authorized by the copyright owner, its agent, or the law; and
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WHERE APPROPRIATE.

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ANY NATURE WHATSOEVER, RESULTING FROM YOUR ACCESS TO AND USE OF OUR WEBSITE, (III) ANY UNAUTHORIZED ACCESS TO OR USE OF OUR SECURE SERVERS AND/OR
ANY AND ALL PERSONAL INFORMATION AND/OR FINANCIAL INFORMATION STORED THEREIN, (IV) ANY INTERRUPTION OR CESSATION OF TRANSMISSION TO OR FROM OUR

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You agree to defend, indemnify and hold harmless YouTube, its parent corporation, officers, directors, employees and agents, from and against any and all claims, damages, obligations, losses,
liabilities, costs or debt, and expenses (including but not limited to attorney's fees) arising from: (i) your use of and access to the YouTube Website; (ii) your violation of any term of these Terms of
Service; (iii) your violation of any third party right, including without limitation any copyright, property, or privacy right; or (iv) any claim that one of your User Submissions caused damage to a third
party. This defense and indemnification obligation will survive these Terms of Service and your use of the YouTube Website.

12. Ability to Accept Terms of Service

You affirm that you are either more than 18 years of age, or an emancipated minor, or possess legal parental or guardian consent, and are fully able and competent to enter into the terms,
conditions, obligations, affirmations, representations, and warranties set forth in these Terms of Service, and to abide by and comply with these Terms of Service. In any case, you affirm that you
are over the age of 13, as the YouTube Website is not intended for children under 13. If you are under 13 years of age, then please do not use the YouTube Website. There are lots of other
great web sites for you. Talk to your parents about what sites are appropriate for you.

13. Assignment

These Terms of Service, and any rights and licenses granted hereunder, may not be transferred or assigned by you, but may be assigned by YouTube without restriction.

14. General

You agree that: (i) the YouTube Website shall be deemed solely based in California; and (ii) the YouTube Website shall be deemed a passive website that does not give rise to personal
jurisdiction over YouTube, either specific or general, in jurisdictions other than California. These Terms of Service shall be governed by the internal substantive laws of the State of California,
without respect to its conflict of laws principles. Any claim or dispute between you and YouTube that arises in whole or in part from your use of the YouTube Website shall be decided exclusively
by a court of competent jurisdiction located in Santa Clara County, California. These Terms of Service, together with the Privacy Notice at http://www.youtube.com/t/privacy and any other legal
notices published by YouTube on the Website, shall constitute the entire agreement between you and YouTube concerning the YouTube Website. If any provision of these Terms of Service is
deemed invalid by a court of competent jurisdiction, the invalidity of such provision shall not affect the validity of the remaining provisions of these Terms of Service, which shall remain in full force
and effect. No waiver of any term of this these Terms of Service shall be deemed a further or continuing waiver of such term or any other term, and YouTube's failure to assert any right or
provision under these Terms of Service shall not constitute a waiver of such right or provision. YouTube reserves the right to amend these Terms of Service at any time and without notice, and it

is your responsibility to review these Terms of Service for any changes. Your use of the YouTube Website following any amendment of these Terms of Service will signify your assent to and
acceptance of its revised terms. YOU AND YOUTUBE AGREE THAT ANY CAUSE OF ACTION ARISING OUT OF OR RELATED TO THE YOUTUBE WEBSITE MUST COMMENCE WITHIN ONE
(1) YEAR AFTER THE CAUSE OF ACTION ACCRUES. OTHERWISE, SUCH CAUSE OF ACTION IS PERMANENTLY BARRED

TERMS AND CONDITIONS

A. ITUNES STORE, MAC APP STORE, APP STORE, AND IBOOKSTORE TERMS OF SALE
B. ITUNES STORE TERMS AND CONDITIONS
C. MAC APP STORE, APP STORE AND IBOOKSTORE TERMS AND CONDITIONS

THE LEGAL AGREEMENTS SET OUT BELOW GOVERN YOUR USE OF THE ITUNES STORE, MAC APP STORE, APP STORE, AND IBOOKSTORE SERVICES ("SERVICES"). TO AGREE TO THESE TERMS, CLICK "AGREE." IF YOU DO NOT AGREE TO THESE TERMS, DO NOT CLICK "AGREE," AND DO NOT USE THE SERVICES.

A. ITUNES STORE, MAC APP STORE, APP STORE, AND IBOOKSTORE TERMS OF SALE

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You agree that you will pay for all products you purchase through the Services, and that Apple may charge your payment method for any products purchased and for any additional amounts (including any taxes and late fees, as applicable) that may be accrued by or in connection with your Account. YOU ARE RESPONSIBLE FOR THE TIMELY PAYMENT OF ALL FEES AND FOR PROVIDING APPLE WITH A VALID PAYMENT METHOD FOR PAYMENT OF ALL FEES. For details of how purchases are billed please visit support.apple.com/kb/HT5582.

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By pre-ordering products, you are authorizing the Services to automatically charge your account and download the product when it becomes available. You may cancel your pre-order prior to the time the item becomes available.

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Apple is not responsible for typographic errors.

B. ITUNES STORE TERMS AND CONDITIONS

THIS LEGAL AGREEMENT BETWEEN YOU AND APPLE INC. ("APPLE") GOVERNS YOUR USE OF THE ITUNES STORE SERVICE (THE “ITUNES SERVICE”).

THE ITUNES STORE SERVICE

Apple is the provider of the iTunes Service, which permits you to purchase or rent digital content ("iTunes Products") for end user use only under the terms and conditions set forth in this Agreement.

REQUIREMENTS FOR USE OF THE ITUNES SERVICE

This iTunes Service is available for individuals aged 13 years or older. If you are 13 or older but under the age of 18, you should review this Agreement with your parent or guardian to make sure that you and your parent or guardian understand it.

The iTunes Service is available to you only in the United States, its territories, and possessions. You agree not to use or attempt to use the iTunes Service from outside these locations. Apple may use technologies to verify your compliance.

Use of the iTunes Service requires compatible devices, Internet access, and certain software (fees may apply); may require periodic updates; and may be affected by the performance of these factors. High-speed Internet access is strongly recommended for regular use and is required for video. The latest version of required software is recommended to access the iTunes Service and may be required for certain transactions or features and to download iTunes Products previously purchased from the iTunes Service. You agree that meeting these requirements, which may change from time to time, is your responsibility. The iTunes Service is not part of any other product or offering, and no purchase or obtaining of any other product shall be construed to represent or guarantee you access to the iTunes Service.

YOUR ACCOUNT

As a registered user of the iTunes Service, you may establish an account ("Account"). Don’t reveal your Account information to anyone else. You are solely responsible for maintaining the confidentiality and security of your Account and for all activities that occur on or through your Account, and you agree to immediately notify Apple of any security breach of your Account. Apple shall not be responsible for any losses arising out of the unauthorized use of your Account.

In order to purchase and download iTunes Products from the iTunes Service, you must enter your Apple ID and password to authenticate your Account. Once you have authenticated your Account, you will not need to

authenticate again for fifteen minutes. During this time, you will be able to purchase and download iTunes Products without re-entering your password. You can turn off the ability to make iTunes Product purchases by adjusting the settings on your computer or iOS Device. For more information, please see http://support.apple.com/kb/HT1904 or http://support.apple.com/kb/HT4213.

You agree to provide accurate and complete information when you register with, and as you use, the iTunes Service ("iTunes Registration Data"), and you agree to update your iTunes Registration Data to keep it accurate and complete. You agree that Apple may store and use the iTunes Registration Data you provide for use in maintaining and billing fees to your Account.

AUTOMATIC DELIVERY AND DOWNLOADING PREVIOUS PURCHASES

When you first acquire music iTunes Products and music video iTunes Products (collectively, “iTunes Auto-Delivery Content”), you may elect to automatically receive (“auto-download”) copies of such iTunes Auto-Delivery Content on additional compatible iOS Devices and iTunes-authorized computers with compatible software by associating such iOS Devices and computers subject to the association rules below (each, an “Associated Device”). For each Associated Device, you may specify which type of iTunes Auto-Delivery Content, if any, may be auto-downloaded to it. On an Associated Device that is capable of receiving push notifications (“Push-Enabled”), including iOS Devices, the iTunes Auto-Delivery Content will auto-download to that Associated Device when it has an Internet connection; on an Associated Device that is not Push-Enabled, including those running on the Windows operating system, iTunes Auto-Delivery Content will automatically appear in the download queue and you may manually initiate the download within iTunes.

As an accommodation to you, subsequent to acquiring iTunes Auto-Delivery Content, purchased (i.e. not rented) movies iTunes Products and TV show iTunes Products (each, “iTunes Eligible Content”), you may download certain of such previously-purchased iTunes Eligible Content onto any Associated Device. Some iTunes Eligible Content that you previously purchased may not be available for subsequent download at any given time, and Apple shall have no liability to you in such event. As you may not be able to subsequently download certain previously-purchased iTunes Eligible Content, once you download an item of iTunes Eligible Content, it is your responsibility not to lose, destroy, or damage it, and you may want to back it up.

Association of Associated Devices is subject to the following terms:

(i) You may auto-download iTunes Auto-Delivery Content or download previously-purchased iTunes Eligible Content from an Account on up to 10 Associated Devices, provided no more than 5 are iTunes-authorized computers.

(ii) An Associated Device can be associated with only one Account at any given time.

(iii) You may switch an Associated Device to a different Account only once every 90 days.

(iv) You may download previously-purchased free content onto an unlimited number of devices while it is free on the iTunes Service, but on no more than 5 iTunes-authorized computers.

An Apple TV is not an “Associated Device.” However, TV show iTunes Products and purchased (i.e. not rented) movies iTunes Products may be played back on compatible Apple TVs, provided that you may only play back any such TV show or movie on a limited number of Apple TVs at the same time.

Some pieces of iTunes Eligible Content may be large, and significant data charges may result from delivery of such iTunes Eligible Content over a data connection.

ITUNES MATCH

iTunes Match permits you to remotely access your matched or uploaded songs, and music videos you have purchased with your Account, along with related metadata, playlists, and other information about your iTunes Library ("iTunes Match Content").

You may subscribe to iTunes Match for an annual fee. You must have a valid credit card on file with iTunes to subscribe. The subscription is non-refundable (except as required by applicable law), and will automatically renew for one-year periods until you cancel. Your account will be charged no more than 24 hours prior to the expiration of the current subscription period. You may cancel automatic renewal by adjusting the iTunes Store account settings on your computer. You will no longer be able to access your iTunes Match Content from iTunes Match after the end of your subscription period.

iTunes Match works with libraries that contain up to 25,000 songs which are either (i) not currently available on the iTunes Service, or (ii) not purchased from the iTunes Service with your Account. Songs that do not meet certain quality criteria or that are not authorized for your computer are not eligible for iTunes Match.

iTunes Match will automatically scan the song files and collect other information that may be used to identify media in your iTunes library, such as the names of songs, song artists or song durations. iTunes Match will use this information to match songs to those currently available on the iTunes Store, and will make matched songs available to you in a format then available on the iTunes Store. If the song is not successfully matched, your copy of the song will be uploaded to Apple in the same format or a format determined by Apple. Apple reserves the right to limit types of content uploaded (for example, excessively large files). Matched or uploaded songs and related metadata will be available for access from an Associated Device that has been enabled for iTunes Match. Association of Associated Devices for iTunes Match is subject to the same terms as Automatic Delivery and Downloading Previous Purchases, and uploaded or matched songs and related information are deemed to be "iTunes Eligible Content." You may also access iTunes Match Content from compatible Apple TVs, provided that you may only do so on a limited number of Apple TVs at the same time.

When you use iTunes Match, Genius will begin associating information about the media in your iTunes library with your Account; the association with your Account will continue for a period of time after your subscription ends. Apple will otherwise use this information as described in the Privacy Section of this Agreement. You will not be able to disable Genius while using iTunes Match, so if you prefer that we do not collect and use information from your iTunes library in this manner, you should not use iTunes Match.

You hereby agree to use iTunes Match only for lawfully acquired content. Any use for illegitimate content infringes the rights of others and may subject you to civil and criminal penalties, including possible monetary damages, for copyright infringement.

iTunes Match is provided on an "AS IS" basis and may contain errors or inaccuracies that could cause failures, corruption or loss of data and/or information, including music, playlist, and play history, from your computer or device and from peripherals (including, without limitation, servers and other computers) connected thereto. You should back up all data and information on your computer or device and any peripherals prior to using iTunes Match. You expressly acknowledge and agree that all use of iTunes Match is at your sole risk. To the extent permitted by law, Apple shall have no liability with respect to your use of iTunes Match, including the inability to access matched or uploaded content.

PRIVACY

The iTunes Service is subject to Apple's Privacy Policy at http://www.apple.com/privacy/.

When you opt in to the Genius feature, Apple will, from time to time, automatically collect information that can be used to identify media in your iTunes library on this computer, such as your play history and playlists. This includes media purchased through iTunes and media obtained from other sources. This information will be stored anonymously and will not be associated with your name or Account. When you use the Genius feature, Apple will use this information and the contents of your iTunes library, as well as other information, to give personalized recommendations to you.

Apple may only use this information and combine it with aggregated information from the iTunes libraries of other users who also opt in to this feature, your iTunes Store purchase history data, aggregated purchase history data from other iTunes Store users, and other information obtained from third parties, to:

• Create personalized playlists for you from your iTunes library.

• Provide you with recommendations regarding media and other products and services that you may wish to purchase.

• Provide recommendations regarding products and services to other users.

At all times your information will be treated in accordance with Apple's Privacy Policy.

Once you opt in to the Genius feature in iTunes, you will be able to create Genius playlists on Genius-capable devices. To enable the Genius feature on a device, you must sync it with your iTunes library after you have opted in.

If you prefer that we do not collect and use information from your iTunes library in this manner, you should not enable the Genius feature. You can revoke your opt-in choice at any time by turning off the Genius feature from the Store menu in iTunes on your computer. After you opt out, iTunes will no longer send information about your iTunes library to Apple. If you have elected to share your library from multiple computers, you need to turn off the Genius feature from each computer. The Genius feature cannot be enabled or disabled from your device.

By opting in to the Genius feature, you consent to the use of your information as described above and as described in Apple's Privacy Policy.

CONTENT AVAILABILITY

Apple reserves the right to change content options (including eligibility for particular features) without notice. For further information or concerns about closed captioning in specific content within the iTunes Store, please emailaccessibility@apple.com. You may also contact Thomas Montgomery, Accessibility Response Engineer, 1 Infinite Loop, Cupertino, California 95014, Phone/Fax: 408-783-5512.

USE OF PURCHASED OR RENTED CONTENT

You agree that the iTunes Service and certain iTunes Products include security technology that limits your use of iTunes Products and that, whether or not iTunes Products are limited by security technology, you shall use iTunes Products in compliance with the applicable usage rules established by Apple and its licensors ("Usage Rules"), and that any other use of the iTunes Products may constitute a copyright infringement. Any security technology is an inseparable part of the iTunes Products. Apple reserves the right to modify the Usage Rules at any time. You agree not to violate, circumvent, reverse-engineer, decompile, disassemble, or otherwise tamper with any of the security technology related to such Usage Rules for any reason—or to attempt or assist another

person to do so. Usage Rules may be controlled and monitored by Apple for compliance purposes, and Apple reserves the right to enforce the Usage Rules without notice to you. You agree not to access the iTunes Service by any means other than through software that is provided by Apple for accessing the iTunes Service. You shall not access or attempt to access an Account that you are not authorized to access. You agree not to modify the software in any manner or form, or to use modified versions of the software, for any purposes including obtaining unauthorized access to the iTunes Service. Violations of system or network security may result in civil or criminal liability.

USAGE RULES

(i) You shall be authorized to use iTunes Products only for personal, noncommercial use.

(ii) You shall be authorized to use iTunes Products on five iTunes-authorized devices at any time, except for Content Rentals (see below).

(iii) You shall be able to store iTunes Products from up to five different Accounts at a time on compatible devices, provided that each iPhone may sync tone iTunes Products with only a single iTunes-authorized device at a time, and syncing an iPhone with a different iTunes-authorized device will cause tone iTunes Products stored on that iPhone to be erased.

(iv) You shall be authorized to burn an audio playlist up to seven times.

(v) You shall not be entitled to burn video iTunes Products or tone iTunes Products.

(vi) iTunes Plus Products do not contain security technology that limits your usage of such products, and Usage Rules (ii) – (v) do not apply to iTunes Plus Products. You may copy, store, and burn iTunes Plus Products as reasonably necessary for personal, noncommercial use.

(vii) You shall be able to manually sync a movie from at least one iTunes-authorized device to devices that have manual sync mode, provided that the movie is associated with an Account on the primary iTunes-authorized device, where the primary iTunes-authorized device is the one that was first synced with the device or the one that you subsequently designate as primary using iTunes.

(viii) An HDCP connection is required to view content transmitted over HDMI.

(ix) Content Rentals

(a) Content rentals are viewable on only one device at a time. You must be connected to the iTunes Service when moving rentals, and you may do so only between your computer and other compatible devices. Content rented using your Apple TV, iPad, iPhone 4, or iPod touch (4th generation) may not be moved. If you move a rental to a compatible device and then use the iTunes Service to restore that device, or choose Settings > Reset > Erase all content and settings on that device, the rental will be permanently deleted.

(b) Once you purchase a rental, you must fully download the rental within thirty (30) days. You have thirty (30) days after downloading a rental to begin viewing. Once you begin viewing, you have twenty-four (24) hours to finish viewing a movie. Stopping, pausing, or restarting a rental does not extend the available time for viewing.

Some iTunes Products, including but not limited to Content rentals, may be downloaded only once and cannot be replaced if lost for any reason. It is your responsibility not to lose, destroy, or damage iTunes Products once downloaded, and you may wish to back them up.

The delivery of iTunes Products does not transfer to you any commercial or promotional use rights in the iTunes Products. Any burning or exporting capabilities are solely an accommodation to you and shall not constitute a grant, waiver, or other limitation of any rights of the copyright owners in any content embodied in any iTunes Product.

You acknowledge that, because some aspects of the iTunes Service, iTunes Products, and administration of the Usage Rules entails the ongoing involvement of Apple, if Apple changes any part of or discontinues the iTunes Service, which Apple may do at its election, you may not be able to use iTunes Products to the same extent as prior to such change or discontinuation, and that Apple shall have no liability to you in such case.

SEASON PASS, MULTI-PASS, ITUNES PASS

The full price of the Season Pass, Multi-Pass, or iTunes Pass is charged upon purchase. You must connect to the iTunes Service and download any remaining Pass content within 90 days after the final Pass content becomes available (or such other time period as may be specified on the purchase page), after which that content may no longer be available for download as part of the purchase. If automatic renewal is selected when you purchase a Multi-Pass, you will be charged the full price of each subsequent Multi-Pass cycle, unless and until you cancel automatic renewal prior to the beginning of the subsequent Multi-Pass cycle (in the Manage Passes section of your Account information). If a network or studio delivers fewer TV episodes than planned when you purchased a Season Pass, we will credit to your Account the retail value of the corresponding number of episodes.

HIGH-DEFINITION (HD) ITUNES PRODUCTS

HD iTunes Products are viewable only on HD capable devices; however, HD iTunes Products purchased (not rented) include a standard-definition version for use on non-HD devices.

SUBMISSIONS TO THE ITUNES SERVICE

The iTunes Service may offer interactive features that allow you to submit materials (including links to third-party content) on areas of the iTunes Service accessible and viewable by the public. You agree that any use by you of such features, including any materials submitted by you, shall be your sole responsibility, shall not infringe or violate the rights of any other party or violate any laws, contribute to or encourage infringing or otherwise unlawful conduct, or otherwise be obscene, objectionable, or in poor taste. You also agree that you have obtained all necessary rights and licenses. You agree to provide accurate and complete information in connection with your submission of any materials on the iTunes Service. You hereby grant Apple a worldwide, royalty-free, nonexclusive license to use such materials as part of the iTunes Service, and in relation to iTunes Products, without any compensation or obligation to you. Apple reserves the right to not post or publish any materials, and to remove or edit any material, at any time in its sole discretion without notice or liability.

Apple has the right, but not the obligation, to monitor any materials submitted by you or otherwise available on the iTunes Service, to investigate any reported or apparent violation of this Agreement, and to take any action that Apple in its sole discretion deems appropriate, including, without limitation, termination hereunder or under Apple's Copyright Policy (http://www.apple.com/legal/copyright.html).

THIRD-PARTY MATERIALS

Certain content, iTunes Products, and services available via the iTunes Service may include materials from third parties. Apple may provide links to third-party websites as a convenience to you. You agree that Apple is not responsible for examining or evaluating the content or accuracy and Apple does not warrant and will not have

any liability or responsibility for any third-party materials or websites, or for any other materials, products, or services of third parties. You agree that you will not use any third-party materials in a manner that would infringe or violate the rights of any other party and that Apple is not in any way responsible for any such use by you.

OBJECTIONABLE MATERIAL

You understand that by using the iTunes Service, you may encounter material that you may deem to be offensive, indecent, or objectionable, and that such content may or may not be identified as having explicit material. Nevertheless, you agree to use the iTunes Service at your sole risk and Apple shall have no liability to you for material that may be found to be offensive, indecent, or objectionable. iTunes Product types and descriptions are provided for convenience, and you agree that Apple does not guarantee their accuracy.

IMPORTANT SAFETY INFORMATION

To avoid muscle, joint, or eye strain during your use of the products offered through the iTunes Service, you should always take frequent breaks, and take a longer rest if you experience any soreness, fatigue, or discomfort. A very small percentage of people may experience seizures or blackouts when exposed to flashing lights or patterns, including but not limited to while playing video games or watching videos. Symptoms may include dizziness, nausea, involuntary movements, loss of awareness, altered vision, tingling, numbness, or other discomforts. Consult a doctor before using the products offered through the iTunes Service if you have ever suffered these or similar symptoms, and stop using such products immediately and see a doctor if they occur during your use of such products. Parents should monitor their children’s use of the products offered through the iTunes Service for signs of symptoms.

INTELLECTUAL PROPERTY

You agree that the iTunes Service, including but not limited to iTunes Products, graphics, user interface, audio clips, video clips, editorial content, and the scripts and software used to implement the iTunes Service, contains proprietary information and material that is owned by Apple and/or its licensors, and is protected by applicable intellectual property and other laws, including but not limited to copyright. You agree that you will not use such proprietary information or materials in any way whatsoever except for use of the iTunes Service in compliance with this Agreement. No portion of the iTunes Service may be reproduced in any form or by any means, except as expressly permitted in these terms. You agree not to modify, rent, lease, loan, sell, distribute, or create derivative works based on the iTunes Service in any manner, and you shall not exploit the iTunes Service in any unauthorized way whatsoever, including, but not limited to, by trespass or burdening network capacity.

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• Provide recommendations to other users.

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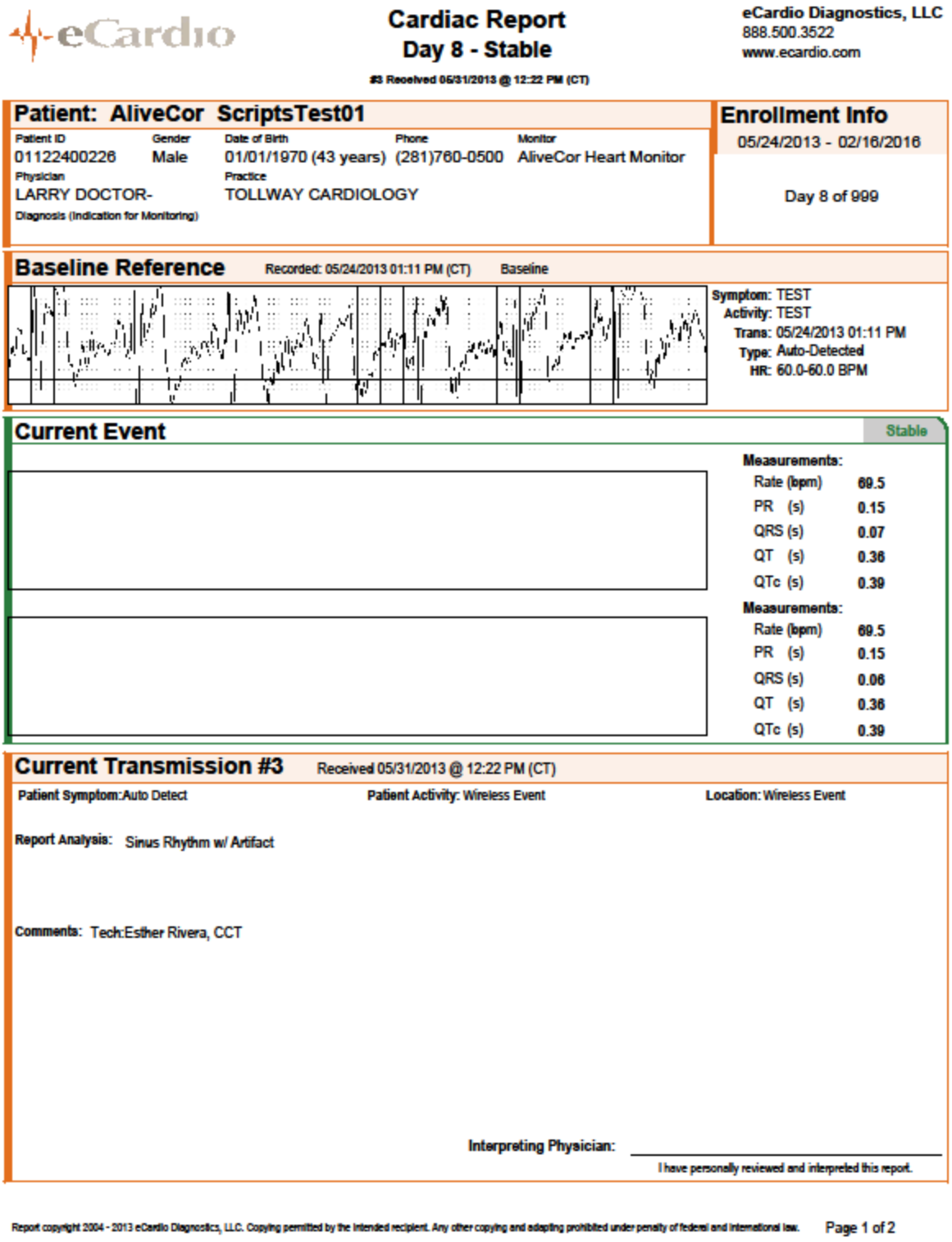
Last Updated: December 3, 2012

Appendix 19: Sample eCardio Report



eCardio

Cardiac Report
Day 8 - Stable

#3 Received 05/31/2013 @ 12:22 PM (CT)

eCardio Diagnostics, LLC
888.500.3522
www.ecardio.com

Patient: AliveCor ScriptsTest01

Patient ID	Gender	Date of Birth	Phone	Monitor
01122400226	Male	01/01/1970 (43 years)	(281)760-0500	AliveCor Heart Monitor

Physician: LARRY DOCTOR-
Practice: TOLLWAY CARDIOLOGY
Diagnosis (Indication for Monitoring)

Enrollment Info
05/24/2013 - 02/16/2016
Day 8 of 999

Baseline Reference Recorded: 05/24/2013 01:11 PM (CT) Baseline

Symptom: TEST
Activity: TEST
Trans: 05/24/2013 01:11 PM
Type: Auto-Detected
HR: 60.0-60.0 BPM

Current Event Stable

Measurements:	
Rate (bpm)	69.5
PR (s)	0.15
QRS (s)	0.07
QT (s)	0.36
QTc (s)	0.39

Measurements:	
Rate (bpm)	69.5
PR (s)	0.15
QRS (s)	0.06
QT (s)	0.36
QTc (s)	0.39

Current Transmission #3 Received 05/31/2013 @ 12:22 PM (CT)

Patient Symptom: Auto Detect
Patient Activity: Wireless Event
Location: Wireless Event

Report Analysis: Sinus Rhythm w/ Artifact

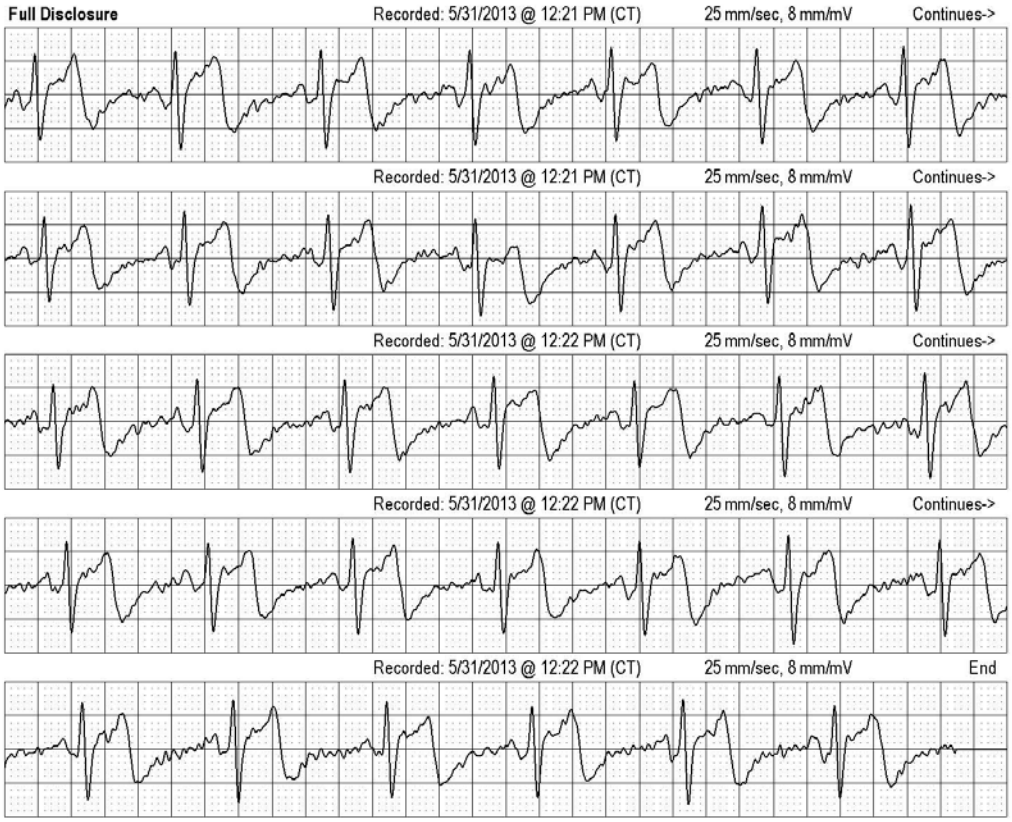
Comments: Tech:Esther Rivera, CCT

Interpreting Physician: _____
I have personally reviewed and interpreted this report.

 Page 1 of 2

Patient: **AliveCor ScriptsTest01** **Stable** Physician: LARRY DOCTOR-WOODLANDS

D.O.B.: 01/01/1970 Age: 43 Gender: Male Dx/Sx:



Appendix 20: E-mail to Scripps Employees

Dear Colleague,

The Scripps Translational Science (STSI) Institute in collaboration with Scripps Wellness has launched the **"Wired for Health"** study to evaluate whether patient use of iPhone 4s together with mobile health devices can reduce health care costs.

STSI is recruiting 200 Scripps employees and family members with one or more of the following conditions: diabetes, high blood pressure and heart arrhythmias.

The people enrolled in the study will be those who have seen their doctor often or have been to the hospital over the past year. The potential study participants will be identified by HealthComp, the administrator for Scripps Health employee medical claims. Their information will be kept strictly confidential.

Half of the participants will make up the control group, while the other half will receive a wireless device to monitor their condition together with an iPhone 4. Both the control and monitoring group participants will be enrolled in HealthComp's Disease Management program, which includes one-on-one contact with a Health Comp nurse and condition-specific health education.

The purpose of the study is to see whether patients who actively track their health conditions through mobile devices linked with a web-based health portal will have more success managing their health conditions and, as a result, spend fewer health care dollars.

If you or a family member (covered under your Scripps insurance plan) have been diagnosed with one or more of the following: **diabetes, high blood pressure or cardiac arrhythmia**, you may be eligible to participate in the "Wired for Health" study. To learn more, please contact Health Comp at 1-800-442-7247 ext 2544 or email wellness@healthcomp.com.

For more information go to: http://www.scripps.org/news_items/4557-scripps-launches-study-to-assess-role-of-mobile-health-devices-in-lowering-health-costs

Sincerely,

Vic Buzachero
Corporate Senior Vice President
Human Resources, Innovation and Performance Management

Appendix 21

SCRIPPS WIRED FOR HEALTH STUDY – 6 MONTH SURVEY

III. Health History

1 How is your health? (pull down: very good, good, average, poor, very poor)

2 In the past 6 months, how many times per week do you/did you use tobacco (if you are a current or previous user of tobacco)?

3 In the past 6 months, how many alcoholic drinks per week do you/did you have (if you are a current or previous drinker)?

4 List any and all additional health conditions that you have been told by a doctor or other health professional that you currently have.

5 Please list all of the medications for which you currently have a prescription from a doctor or other health professional.

6 Have you experienced any changes in your health during the past 6 months?

II. Health Literacy (single item)

Over the past 6 months, how often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy? (pull down: Never, Rarely, Sometimes, Often, and Always)

III. Perceived Health Services Utilization (PERC)

1 Please answer the following:

a. In the past 6 months, how many times did you visit a physician? Do **not** include visits while in the hospital or to a hospital emergency room. Fill in with “0” or another number. ____times

b. In the past 6 months, how many times did you go to a **hospital** emergency room? Fill in with “0” or another number. ____times

c. How many different **times** did you stay in a hospital **overnight** or longer in the past 6 months? Fill in with “0” or another number. ____times

d. How many total **nights** did you spend in the hospital in the past 6 months? Fill in with “0” or another number. ____nights

IV. Health Locus of Control (MHL Form C)

Each item below is a belief statement about your medical condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer **EVERY ITEM** and that you circle **ONLY ONE** number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

		Strongly Disagree	**Moderately Disagree**	**Slightly Disagree**	**Slightly Agree**	**Moderately Agree**	**Strongly Agree**
1	If my condition worsens, it is my own behavior which determines how soon I will feel better again.	1	2	3	4	5	6
2	As to my condition, what will be will be.	1	2	3	4	5	6
3	If I see my doctor regularly, I am less likely to have problems with my condition.	1	2	3	4	5	6
4	Most things that affect my condition happen to me by chance.	1	2	3	4	5	6
5	Whenever my condition worsens, I should consult a medically trained professional.	1	2	3	4	5	6
6	I am directly responsible for my condition getting better or worse.	1	2	3	4	5	6
7	Other people play a big role in whether my condition improves, stays the same, or gets worse.	1	2	3	4	5	6
8	Whatever goes wrong with my condition is my own fault.	1	2	3	4	5	6
9	Luck plays a big part in determining how my condition improves.	1	2	3	4	5	6
10	In order for my condition to improve, it is up to other people to see that the right things happen.	1	2	3	4	5	6
11	Whatever improvement occurs with my condition is largely a matter of good fortune.	1	2	3	4	5	6
12	The main thing which affects my condition is what I myself do.	1	2	3	4	5	6
13	I deserve the credit when my condition improves and the blame when it gets worse.	1	2	3	4	5	6
14	Following doctor's orders to the letter is the best way to keep my condition from getting any worse.	1	2	3	4	5	6
15	If my condition worsens, it's a matter of fate.	1	2	3	4	5	6
16	If I am lucky, my condition will get better.	1	2	3	4	5	6

17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself.	1	2	3	4	5	6
18	The type of help I receive from other people determines how soon my condition improves.	1	2	3	4	5	6

V. Health Self-Efficacy (SE for Managing Chronic Disease 6-Item Scale)

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

not at all | | | | | | | | | totally confident 1 2 3 4 5 6 7 8 9 10 confident

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all | | | | | | | | | totally confident 1 2 3 4 5 6 7 8 9 10 confident

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all | | | | | | | | | totally confident 1 2 3 4 5 6 7 8 9 10 confident

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all | | | | | | | | | totally confident 1 2 3 4 5 6 7 8 9 10 confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

not at all | | | | | | | | | totally confident 1 2 3 4 5 6 7 8 9 10 confident

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

not at all | | | | | | | | | totally confident 1 2 3 4 5 6 7 8 9 10 confident

VI. Patient Activation (Me and My Health)

INSTRUCTIONS: For each statement below please mark an X in the box to the right that best describes how much you disagree—agree with the statement as it applies to you personally.

There are no right or wrong answers. Your answers should be what is true to you and not just what you think the doctor wants you to say.

		Strongly Disagree	Disagree	Agree	Strongly Agree
1	When all is said and done, I am the person who is responsible for managing my health condition.				
2	Taking an active role in my own health care is the most important factor in determining my health and ability to function.				
3	I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition.				
4	I know what each of my prescribed medications do.				
5	I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself.				
6	I am confident I can tell a doctor concerns I have even when he or she does not ask.				
7	I am confident that I can follow through on medical treatments I need to do at home.				
8	I understand the nature and causes of my health condition(s).				
9	I know the different medical treatment options available for my health condition.				
10	I have been able to maintain the lifestyle changes for my health condition that I have made.				
11	I know how to prevent further problems with my health condition.				
12	I am confident I can figure out solutions when new situations or problems arise with my health conditions.				
13	I am confident that I can maintain lifestyle changes, like diet and exercise, even during times of stress.				

VII. Health-Related Quality of Life (SF12)

For each of the following questions, please circle the number that best describes your answer.

1. In general, would you say your health is:
_____ Excellent (1)
_____ Very Good (2)
_____ Good (3)
_____ Fair (4)
_____ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
_____ Yes, Limited A Lot (1)
_____ Yes, Limited A Little (2)
_____ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:
_____ Yes, Limited A Lot (1)
_____ Yes, Limited A Little (2)
_____ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
_____ Yes (1)
_____ No (2)

5. Were limited in the KIND of work or other activities:
_____ Yes (1)
_____ No (2)

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:
_____ Yes (1)
_____ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:
_____ Yes (1)
_____ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

_____ Not At All (1)
_____ A Little Bit (2)
_____ Moderately (3)
_____ Quite A Bit (4)
_____ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

10. Did you have a lot of energy?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

11. Have you felt downhearted and blue?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

VIII. Physician Communication

The purpose of this questionnaire is to obtain your views about your communications with your **physician (the one you see most often) about your medical problems over the past 6 months.** Please show how strongly you agree or disagree with these statements by **checking the box that best fits your views.**

		Strongly Disagree	Disagree	Slightly Disagree	Not Sure	Slightly Agree	Agree	Strongly Agree
I DO A GOOD JOB OF:								
1.	Explaining my medical problem.							
2.	Describing the symptoms of my medical problem(s).							
3.	Answering the doctor's questions thoroughly.							
4.	Answering the doctor's questions honestly.							
5.	Letting the doctor know when I didn't understand something.							
6.	Getting answers to my questions.							
7.	Getting all the information I need.							
MY PHYSICIAN EXPLAINS THE FOLLOWING TO MY SATISFACTION:								
1.	Explaining what my medical problems are.							
2.	Explaining the possible causes of my medical problems.							
3.	Explaining what I may be able to do to get better.							
4.	Reviewing or repeating important information.							
5.	Making sure I understand his/her explanations/directions.							
6.	Using language I can understand.							
7.	Encouraging me to ask questions.							
Please indicate how strongly you agree or disagree with these statements:								
	Overall, I am satisfied with my physician's communication regarding my medical problems.							

IX. Medication Adherence (Morisky 8-Item)

Question		Yes	No
1	Do you sometimes forget to take your medicine?		
2	People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?		
3	Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?		
4	When you travel or leave home, do you sometimes forget to bring along your medicine?		
5	Did you take all your medicines yesterday?		
6	When you feel like your symptoms are under control, do you sometimes stop taking your medicine?		
7	Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

8. How often do you have difficulty remembering to take all your medicine?

__ A. Never/rarely

__ B. Once in a while

__ C. Sometimes

__ D. Usually

__ E. All the time

X. Exercise (GLTEQ)

1. During a typical 7-Day period (a week), how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

	Times Per Week
a) STRENUOUS EXERCISE (HEART BEATS RAPIDLY) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	
b) MODERATE EXERCISE (NOT EXHAUSTING) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	
c) MILD EXERCISE (MINIMAL EFFORT) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	

2. During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
_____	_____	_____

XI. Use of Innovations

1. Please answer the following questions regarding your thoughts, views, and feelings about **new medical tests, treatments, and devices.**

		strongly disagree	disagree	neutral	agree	strongly agree
1.	If I heard of a new medical test, treatment, or device I would try to find out more about it					
2.	Among my friends, I am usually one of the first to find out about and/or utilize a new medical test, treatment, or device					
3.	In general, I am hesitant to undergo or utilize a new medical test, treatment, or device					

2. Please answer the following questions regarding your thoughts, views, and feelings about **the use of medical devices that can be used at home** to monitor various aspects of your health, including blood pressure, blood sugar, and heart rhythms.

		strongly disagree	disagree	neutral	agree	strongly agree
1.	The use of at-home medical devices for health monitoring is consistent with my approach to my health					
2.	The use of at-home medical devices for health monitoring fits well with my values and goals					
3.	The use of at-home medical devices for health monitoring is hard to understand					
4.	The use of at-home medical devices for health monitoring has many different parts					
5.	The use of at-home medical devices for health monitoring can help me stay healthier compared to other strategies, like seeing my doctor more often					

3. Please answer the following:

To me, new digital technologies like the Smart Phone are:

b. important	___:___:___:___:___:___:___	unimportant
c. boring	___:___:___:___:___:___:___	interesting
d. relevant	___:___:___:___:___:___:___	irrelevant
e. exciting	___:___:___:___:___:___:___	unexciting
f. means nothing	___:___:___:___:___:___:___	means a lot to me
g. appealing	___:___:___:___:___:___:___	unappealing
h. fascinating	___:___:___:___:___:___:___	mundane
i. worthless	___:___:___:___:___:___:___	valuable
j. involving	___:___:___:___:___:___:___	uninvolving
k. not needed	___:___:___:___:___:___:___	needed

XIII. Device Usability

Please answer the following in regards to your monitoring device or devices:

System Usability Scale (SUS)

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

XIV. Technology Usability and Satisfaction **(MILES study survey)**

These questions ask about your experience with the device or devices you received for the study.

1	2	3	4
Very Satisfied	**Satisfied**	**Dissatisfied**	**Very Dissatisfied**

___ **1.** Overall, how satisfied are you with your device(s)?

___ **2.** Overall, how easy/difficult was it to use your device(s)?

___ **3.** Overall, my device(s) interrupted my daily activities.

___ **4.** Overall, using my device(s) was an enjoyable experience.

___ **5.** Overall, using my device(s) required too much of my time.

___ **6.** Overall, my device(s) was distracting

___ **7.** Overall, my device(s) distracted me from my work.

___ **8.** Overall, my device(s) distracted me from my household chores.

___ **9.** Overall, my device(s) was uncomfortable to wear/carry around.

10. What do you like the most about your device(s)?

11. What do you like the least about device(s)??

12. I would be willing to participate in a study testing my device(s) again?

***XV. Satisfaction with Remote Monitoring Devices* (MILES study survey)**

We are interested in your experience with the Wired for Health devices. For the device(s) that you were given, please rate how much you agree or disagree with the following statements. 1 =strongly agree, to 6 = strongly disagree.

1	2	3	4	5	6
Stongly Agree	**Agree**	**Slightly Agree**	**Slightly Disagree**	**Disagree**	**Strongly Disagree**

___ **1.** I have found the remote monitoring device(s) easy to use.

___ **2.** The remote monitoring device(s) has been right on target for me.

___ **3.** The contacts I have had with the remote monitoring device(s) were too many.

___ **4.** I could set a personal goal for improving my health on my own than with the remote monitoring device(s).

___ **5.** The length of time needed to use the remote monitoring device(s) has been about right.

___ **6.** I have had a hard time remembering to use the remote monitoring device(s).

___ **7.** The remote monitoring device(s) has given me confidence that I could become more active in managing my condition.

___ **8.** The remote monitoring device(s) feedback has helped me track my health.

___ **9.** The remote monitoring device(s) has helped me track my exercise level.

___ **10.** The remote monitoring device(s) feedback has helped me track my eating.

___ **11.** There has been too little training on how to use the remote monitoring device(s).

___ **12.** The remote monitoring device(s) has motivated me to be active in monitoring my health.

___ **13.** The remote monitoring device(s) has motivated me to increase my exercise level.

___ **14.** The remote monitoring device(s) has motivated me to eat healthier foods.

___ **15.** The remote monitoring device(s) has helped me deal with problems I have had in achieving my health goals.

___ **16.** The remote monitoring device(s) has helped me remember to monitor my condition regularly.

___ **17.** I have found interactions with the remote monitoring device(s) to be boring

___ **18.** The remote monitoring device(s) has helped me understand the benefits of being active in managing my health.

___ **19.** The remote monitoring device(s) feedback I have received have made little difference in how much I have monitored my condition.

Appendix 21

Member Update

Scripps Medical Plans

Receive up to 32 Wellness Points for participating in the **Wired for Health Study**

Dear Member,

Thank you for your continued participation in the Disease Management program. We are pleased to be a part of your health care team.

We are sending you this letter to let you know about the new Scripps **Wired for Health Study** and to see if you might have interest in participating. This unique study is focusing on individuals who have diabetes, high blood pressure or a heart arrhythmia. It will test whether individuals who use remote wireless monitoring devices are better able to control their condition and decrease the cost of their health care over a six month period.

Study participants will be randomly assigned to either the control or monitoring group. Both groups will meet with a study staff member, complete health questionnaires and provide information about their current health conditions. The monitoring group will be provided with up to three devices. These devices include a blood pressure monitor, blood sugar monitor and/or heart monitor based on their current health conditions. All three devices will connect to an iPhone that will also be provided to the monitoring group for the duration of the study.

The **Scripps Wired for Health Study** is voluntary and will not cost you anything to participate. Please consider participating in this great cause!

We thank you for your time and wish you continued good health.

Sincerely,

Wellness Management
Phone: (800) 442-7247
Email: Wellness@HealthComp.com

HealthComp
Third Party Administrators

For more information or signing up:

Call a Health Comp Nurse at 1-800-442-7247 ext. 2507
or
Email: wellness@healthcomp.com

If we don't hear from you, a Nurse will call you in 2-4 weeks to see if you are interested or have any questions

Scripps Translational Science Institute

Appendix 22

Dear Wired for Health Participant,

Thank you for your continued participation in the study. As mentioned at your enrollment visit, your participation in the Wired for Health Study provides an opportunity for you to earn wellness credits. The Scripps wellness program allows participants to complete activities in order to earn credit toward a reduction in health insurance costs. This year the number of credits required for the health insurance incentive has increased to 100. Therefore we are increasing the number of points that will be awarded for participation in the Wired for Health Study. There is a specific structural breakdown of how wellness points must be earned in order to qualify for this incentive. The reason for the specific structure of the program is to promote variety in activities. Please be aware that there is an annual maximum number of credits that can be earned in any given category. In the Wired for Health Study, you were randomized to either the control group or the monitoring group. Both groups will earn 32 wellness points for participation. Points will only be awarded to those who complete the study.

These wellness points will be earned in the following categories:

- 10 credits for Health Coaching (there is a **10 credit maximum** per year)
- 4 credits for Completion of the Baseline Survey and Follow Up Survey (there is a **4 credit maximum** for survey completion each year)
- 18 credits for Personal Health Activities (there is a **36 credit maximum** per year)

Your wellness points for the study will be awarded at the end of the fiscal year – September 2014. Furthermore, the data generated by the wireless devices is not part of your medical record unless you share that information with your healthcare provider.

If you have any questions or concerns on how to achieve the required number of wellness points, the HR team can help answer any questions that may arise for you. Attached you will find a table that shows a breakdown of wellness points and the maximum number for each category.

For general questions pertaining to the Scripps Wellness program contact:

Hamilton Mears
mears.hamilton@scrippshealth.org
(858) 309-2695

Andrea Krakower
krakower.andrea@scrippshealth.org
(858) 380-7445

Sincerely,

The Wired for Health Study Team

Appendix 23

You're Invited!

Wired for Health Study

Details Inside

Scripps Translational Science Institute

You're Invited!

Wired for Health Study

Details Inside

Scripps Translational Science Institute

You're Invited!

Wired for Health Study

Details Inside

Scripps Translational Science Institute

Appendix 24

Dear Study Participant,

You have reached the end of the monitoring portion of the Wired for Health Study. Thank you very much for your participation. This study will help us answer some important questions about the management of chronic diseases and how wireless medical devices might help in that management. To close out your involvement in this study we need you to complete the end of study survey and attend a final study visit, which will be similar to the enrollment visit 6 months ago.

After you complete the survey, a study coordinator will call you to schedule your end of study visit.

Again, thank you for your participation in this important study.

Regards,

The Wired for Health Study Team

HealthComp®
Third Party Administrators
Wellness Management

April 28, 2014

Dear Member,

Please find enclosed two (2) copies of the Wired for Health Consent form. As you read it, you will find three (3) places for your signature. Sign in all three places, and return one copy in the self-addressed stamped envelope, and retain the other copy for your records. After we receive the consent, a link will be sent to your email address to complete the online survey. This survey must be done before a study coordinator will contact you for your appointment.

You may also fax the consent to us at (559) 243 7012. Please use a cover sheet and address it to "WFH" attention Catherine.

Thank you again for your participation in the Wired for Health Study.

Sincerely,

Catherine Rael | HealthComp
Utilization Management
P.O. Box 45018
Fresno, CA 93718-5018
Tel: (800) 442 7247 ext. 2544
Fax: (559)243 7012