OULUN AMMATTIKORKEAKOULU

Miro Kuusijärvi

ÄLYKKÄÄT KULJETTAJAN TUKIJÄRJESTELMÄT JA LÄÄKINNÄLLISEN LAITTEEN KÄYTTÖLIITTYMÄSUUNNITTELUN VAATIMUKSET

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Miro Kuusijärvi
Opinnäytetyö
Syksy 2017
Tieto- ja viestintätekniikan koulutusohjelma
Oulun ammattikorkeakoulu

TIIVISTELMÄ

Oulun ammattikorkeakoulu
Tietotekniikan koulutusohjelma, laite- ja tuotesuunnittelun suuntautumisvaihtoehto

Tekijä: Miro Kuusijärvi
Opinnäytetyön nimi: Älykkäät kuljettajan tukijärjestelmät ja lääkinnällisen laitteen käyttöliittymäsuunnittelun vaatimukset.
Työn ohjaaja: Kari Jyrkkä, Veijo Väisänen
Työn valmistumislukukausi ja -vuosi: Syksy 2017 Sivumäärä: 83

Oulun ammattikorkeakoulun tietotekniikan koulutusohjelmassa on ollut mahdollista suorittaa opinnäytetyö 1–3:ssa osassa. Tämä opinnäytetyö on suoritettu kahdessa osassa, joista ensimmäinen on 5 opintopisteen kokonaisuus. Toinen osa vastaa työmäärältään 10 opintopisteen laajuutta opinnäytetyöstä. Ensimmäinen osa valmistui vuoden 2016 keväällä ja toinen vuoden 2017 syksyllä.

Opinnäytetyön ensimmäinen osa käsittelee älyliikennettä. Tutkimuksessa luodaan katsaus älykkäisiin kuljettajan tukijärjestelmiin ja vertaillaan niissä käytettyjä tutkateknologioita. Tutkiin perustuvien järjestelmien ominaisuuksia vertaillaan konenäöllä toteutettuun ratkaisuun.

Toinen osa tehtiin toimeksiannosta MoveSole Oy:lle. Yhtiö on lääkinnällisten laitteiden tuotekehitykseen erikoistunut yritys, joka toimii Oulussa. Opinnäytetyön tavoitteena oli selvittää lääkinnällisen laitteen käyttöliittymäsuunnittelua koskevat vaatimukset mahdollisimman kattavasti. Lisäksi tavoitteena oli tutkia, mitä vaatimuksia onnistuneet käytettävyystestaukset tuovat mukanaan. Työhön liittyen toteutettiin myös käytettävyystestausprotokolla standardien vaatimalla tavalla.

Asiasanat: koosteopinnäyte, älyliikenne, lääkinnälliset laitteet, käyttöliittymät

SISÄLLYS

1 JOHDANTO

Oulun ammattikorkeakoulun tietotekniikan koulutusohjelmassa on ollut mahdollista suorittaa opinnäytetyö joko yhtenä kokonaisuutena tai pienemmissä osissa. Tällöin kyseessä on niin sanottu koosteopinnäytetyö, jonka ensimmäinen osa suoritetaan toisen opiskeluvuoden keväällä ja viimeinen osa opintojen loppuvaiheessa. Tämän työn ensimmäinen osa valmistui vuoden 2016 keväällä ja jälkimmäinen vuoden 2017 syksyllä. Nämä kaksi osaa eivät liity toisiinsa millään tavalla, koska ensimmäinen osa on teknologiaselvitys jostain tuolloin ajankohtaisesta aiheesta. Jälkimmäinen taas on tehty toimeksiannosta yritykselle.

Työn ensimmäisessä osassa käsitellään älyliikennettä ja kuvaillaan älykkäiden kuljettajatukijärjestelmien toimintaa teknologian kannalta. Työn tarkoituksena oli perehtyä mittaustekniikoihin, joita näissä järjestelmissä käytetään. Tämä osa on laajuudeltaan 5 opintopistettä vastaava kokonaisuus.

Toisen osan aihe saatiin yrityksestä, jossa suoritin myös yrityslähtöiset tuotekehitysprojektit sekä harjoitteluni. Aihe sinällään oli niin monipuolinen, että siitä saatiin helposti työmäärältään 10 opintopisteen paketti. Aiheena oli selvittää huomioitavat lääkinnällisten laitteiden erityisvaatimukset niin lainsäädännön kuin muidenkin suunnitteluperiaatteiden osalta. Lisäksi selvitettiin käytettävyystesteihin liittyviä piirteitä ja todennettiin osaaminen valmistelemalla käytettävyystestiprotokolla tulevia testejä varten.

2 OPINNÄYTETYÖN ENSIMMÄISEN OSAN ESITTELY

Työ (liite 1) suoritettiin keväällä 2016 muiden opintojen ohessa. Työn ohjaajana toimi Kari Jyrkkä. Kirjoitustyö suoritettiin pääasiallisesti Oulun ammattikorkeakoulun tiloissa. Työn aiheena on tuolloin itseäni kiinnostanut ajankohtainen aihealue. Työssä suoritetaan yleiskatsaus älyliikenteen asioihin ja perehdytään tarkemmin älykkäiden kuljettajatukijärjestelmien toimintaan teknologiaselvityksen avulla.

Opinnäytetyön aikana tiedonhakutaitoni kehittyivät huomattavasti. Projektityöskentelytaitoni parantuivat järjestelmällisen suunnittelun kautta. Teknologiaselvityksen aikana perehdyin erilaisiin etäisyydenmittaustekniikoihin ja tutkateknologioihin kattavasti. Myös konenäön toimintaperiaate selventyi selvityksen myötä. Tutustuin samalla myös eri autonvalmistajien tekemiin tutkimuksiin sekä tukijärjestelmien historiaan, jotka ovat myös erittäin mielenkiintoisia aiheita. Pääsin myös pohtimaan näiden järjestelmien vaikutuksia yleisesti liikenneturvallisuuteen sekä luomaan pienen katsauksen tulevaisuuteen.

3 OPINNÄYTETYÖN TOISEN OSAN ESITTELY

MoveSole Oy:n tarjoama aihe oli selvitys lääkinnällisten laitteiden tuotekehitystä, erityisesti käyttöliittymäsuunnittelua koskevien vaatimusten määrittely. EU:n lääkinnällisiä laitteita koskeva lainsäädäntö edellyttää tiettyjä toimintamalleja valmistajilta. Näillä halutaan varmistaa markkinoille tulevien lääkinnällisten laitteiden ehdoton potilasturvallisuus. Ennen kuin tuote voidaan laillisesti tuoda Euroopan markkinoille, valmistajan täytyy osoittaa laitteen yhdenmukaisuus lääkintälaitedirektiivin kanssa. Kun valmistaja on todistanut kykynsä tuottaa määräysten mukaisia laitteita, sille voidaan myöntää CE-merkki.

Työssä (liite 2) selvitetään lainsäädännön asettamat vaatimukset, jotka ovat relevantteja applikaation eli laitteen käyttöliittymän osalta. Työssä selvitetään kaikki harmonisoidut standardit sekä niiden sisältämät vaatimukset, jotka koskevat ohjelmistokehitystä, laadun- ja riskienhallintaa, kotikäyttöä sekä käytettävyyttä. Huomio kiinnitettiin toimeksiantajan pyynnöstä myös käytettävyystestaukseen. Tästä esiteltiin tärkeimmät piirteet sekä valmisteltiin käytettävyystestausprotokolla tulevia testejä varten.

Työn aikana opin todella paljon lääkinnällisen laitteen tuotekehityksen erityispiirteistä. Lisäksi perehdyin käytettävyystestauksen menetelmiin monipuolisesti. Työn lopputuloksena saatiin kattava ohjenuora lääkinnällisen laitteen käyttöliittymäsuunnittelua varten. Lisäksi tuleviin käytettävyystesteihin on nyt saatavilla valmis suunnitelma, josta voidaan pienellä työllä muodostaa eri tilanteisiin sopiva protokolla.

4 YHTEENVETO

Kokonaisuudessaan tämä kaksiosainen opinnäytetyö vastaa 15 opintopisteen työpanosta. Useassa osassa suoritettuna työmäärä tuntui kohtalaisen pieneltä. Toisaalta aiheet eivät nyt liity millään tavalla toisiinsa. Molemmat aiheet kuitenkin liittyvät opiskelemaani alaan läheisesti, ja uskon niistä kertyneistä tiedoista olevan vielä paljon hyötyä tulevaisuudessa. Jälkeenpäin ajateltuna valitsisin nyt suorittamisen kokonaisena 15 opintopisteen pakettina, koska se mahdollistaisi entistäkin syvemmän perehtymisen aiheeseen. Jälkimmäinen osakokonaisuus on kirjoitettu englannin kielellä toimeksiantajan pyynnöstä. Tämä oli oikein hyvä ratkaisu, koska suurin osa lähteistä on englanninkielisiä. Kaiken kaikkiaan työ oli sekä mielenkiintoinen että erittäin monipuolinen.

LIITTEET

Liite 1 Älykkäät kuljettajan tukijärjestelmät

Liite 2 Medical Application Design

LIITE 1

OULUN AMMATTIKORKEAKOULU

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ÄLYKKÄÄT KULJETTAJAN TUKIJÄRJESTELMÄT

LIITE 1

ÄLYKKÄÄT KULJETTAJAN TUKIJÄRJESTELMÄT

Miro Kuusijärvi
Opinnäytetyö osa 1
Kevät 2016
Tietotekniikan koulutusohjelma
Oulun ammattikorkeakoulu

SISÄLLYS

1 JOHDANTO

Esineiden internetin ja siihen liittyvien tekniikoiden kehittyessä haetaan tiedonsiirrolle aina vain uusia käyttötarkoituksia. Keräämällä tietoa ja jakamalla sitä muiden käyttäjien kesken voidaan usein parantaa jo olemassa olevia sovelluksia olennaisesti. Liikenteen parissa älykkäällä teknologialla voidaankin saavuttaa hyötyä monilla eri osa-alueilla. Älyliikenteestä puhutaan silloin, kun liikkumisessa hyödynnetään tieto- ja viestintätekniikkaa toimivuuden, tehokkuuden ja turvallisuuden parantamiseksi. Sellaisia järjestelmiä ovat esimerkiksi ajoneuvojen kuljettajatukijärjestelmät, joukkoliikenteen informaatiopalvelut, liikenneväylien tiedotus- ja ohjausjärjestelmät sekä paikannuspalvelut. (1.)

Toimivuudella tarkoitetaan liikenneväylien sujuvuuden parantamista ja ruuhkien välttämistä ajantasaisen tiedotuksen ja liikenneohjauksen avulla. Turvallisuuden parantaminen on monella tapaa mahdollista nykypäivän teknologian avulla. Voidaan nopeuttaa avun saantia onnettomuustilanteissa, ehkäistä lisäonnettomuuksia ajoneuvojen ja tien välisellä tiedonvaihdolla, estää väylien ruuhkautumista ja välttää kuljettajan virheitä ajoneuvotietojen seurannalla. Mikäli tietojenkeruusta tulee laajamittaista, myös tietoturva-asiat tulevat varmasti tarkemman tarkastelun alle. Tehokkuuden parantaminen lisää samalla ekologisuutta. Siihen voidaan pyrkiä esimerkiksi ajotavan seurannalla tai reittien optimoimisella. Teollisuudesta tuttu juuri ajallaan -käsite (just on time) toteutuu kuljetusten tarkan suunnittelun avulla. Ajantasainen tieto väylien ruuhkautumisesta ja olosuhteista auttaa ajojärjestelijää lähettämään kuljetuksen matkalle parhaimpaan mahdolliseen ajankohtaan. Tällä tavoin myös kuljetusyritysten kalustonkäyttö tehostuu merkittävästi. Nämä kolme painopistealuetta ovat merkittyinä Suomen liikenne- ja viestintäministeriön älyliikennestrategiaan. (1.)

Älykkäitä, ilman kuljettajaa toimivia autoja on mahdollista toteuttaa tämän päivän teknologialla. Tällainen itsenäiseen havainnointiin ja reittisuunnitteluun kykenevä auto vaatii monenlaisia sensoreita ja datayhteyksiä toimiakseen vaaditulla tavalla. Hakukoneyhtiö Google kehittää tällaista autoa parhaillaan Yhdysvalloissa. Auto toimii aidon kuljettajan tavoin erilaisten sensorien avulla, ja pys-

tyy jopa ennakoimaan liikennetilanteita. Keskustelua käydään muun muassa liikenteen turvallisuudesta ja verkkoinfrastruktuurista. Tiedonsiirron tulisi olla luotettavaa ja viiveetöntä. Googlen älyautolle on jo testivaiheessa sattunut useita onnettomuuksia, joten keskustelu turvallisuudesta on todellakin aiheellista. Ihmisen loukkaantumiseen johtaneita onnettomuuksia on kuitenkin ollut verrattain vähän. Täysin aukottomasti ei kukaan ole voinut todistaa tietokoneiden kykyä kuljettaa ihmisiä yhtä turvallisesti, kuin ihminen itse. (2.) Täysin itsenäisesti liikkuviin ajoneuvoihin voidaan tuskin siirtyä vielä aivan lähitulevaisuudessa, mutta tällaiset projektit tuovat parannuksia myös nykyautojen ominaisuuksiin, joiden kuljettamisesta vastaa ihminen. Autoissa onkin nykyään useita erilaisia kuljettajaa avustavia järjestelmiä. Niiden toimintaan tarvitaan yllättävän paljon tietotekniikkaa varmistamaan, että ajoneuvo käyttäytyy oikein ja samalla turvallisesti.

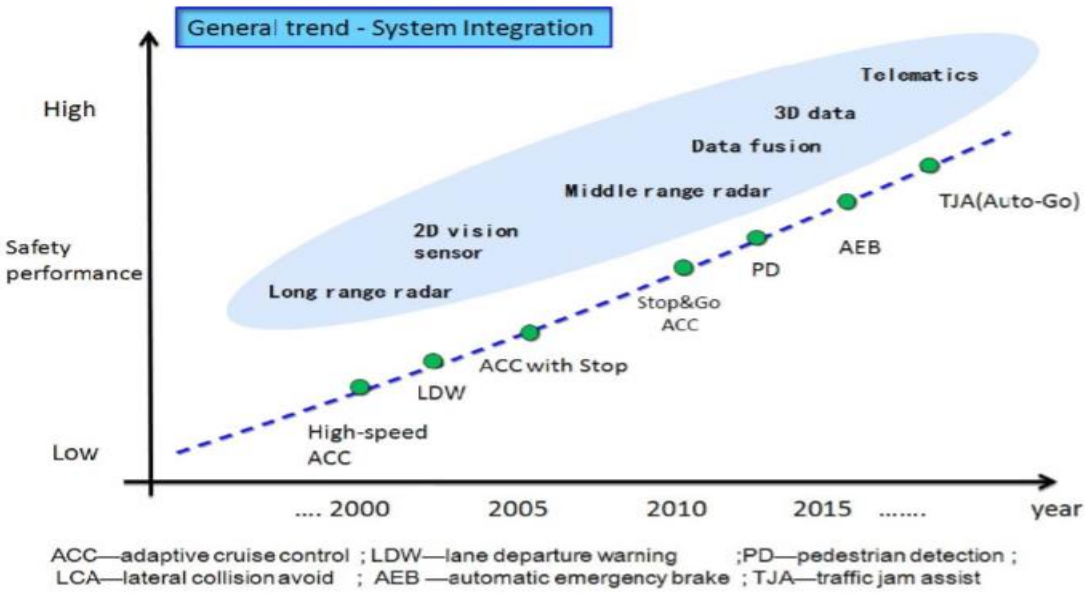
Tämä on ensimmäinen opinnäytetyön kolmesta osasta. Tässä osassa keskitytään tarkemmin älykkäistä avustinjärjestelmistä mielenkiintoisimpaan, eli adaptiiviseen vakionopeudensäätimeen ja sen sensoritekniikkaan perustuviin avustinjärjestelmiin.

2 ADAPTIIVINEN VAKIONOPEUDENSÄÄDIN

2.1 HISTORIAA

Ensimmäisenä autonvalmistajana Mitsubishi toi Japanin markkinoille vuonna 1992 järjestelmän, joka varoitti kuljettajaa vaikuttamatta kiihdytykseen tai jarrutukseen. Se perustui lidar-tekniikkaan (light detection and ranging), eli se hyödynsi lasermittaustekniikkaa ajoneuvojen välisen etäisyyden mittaukseen. Myöhemmin, vuonna 1995, samainen valmistaja kehitteli järjestelmää vieläkin pidemmälle tuoden siihen myös nopeudensäätelytoiminnon mukaan. (3,4.) Eri autonvalmistajilla on erilaisia konfiguraatioita kyseisestä järjestelmästä. Järjestelmä saattaa osallistua jopa ohjaukseenkin.

Järjestelmä on havaittu siinä määrin hyödylliseksi, että sitä kehitetään yhä pidemmälle. Nykypäivänä järjestelmän rinnalla on usein muitakin samoja sensoreita hyödyntäviä avustimia, esimerkiksi törmäysvaroitin. Kuvasta 1 voidaan tarkastella kehityksen edistymistä nykypäivään saakka. Mitä pidemmälle kehitystä viedään, sitä enemmän nämä järjestelmät tuovat turvallisuutta liikenteeseen.



Kuva 1. ACC-järjestelmän kehityksen virstanpylväitä (5)

2.2 ETÄISYYDENMITTAUSTEKNIIKAT

Mukautuva vakionopeudensäädin säilyttää halutun etäisyyden edellä kulkevaan ajoneuvoon, hiljentää tai tarvittaessa lisää nopeutta. Näitä ominaisuuksia varten järjestelmä tarvitsee etäisyys- ja suuntatiedon edellä olevasta ajoneuvosta. Kuljettaja voi säätää nopeuden, jota järjestelmä ei saa ylittää sekä etäisyyden, jolla ajoneuvoa seurataan.

Etäisyyttä voidaan mitata monilla eri tavoilla. Etäisyydenmittaus sensoreilla perustuu aina jonkinlaisen pulssin lähettämiseen ja sen matka-ajan mittaamiseen lähdöstä paluusignaaliin. Nykyään suositaan yleisesti radioaaltotutkaan tai lidar-tekniikkaan perustuvia järjestelmiä. Tulevaisuudessa kameroiden edelleen kehittyessä myös kamerapohjaiset järjestelmät ottanevat yhä enemmän jalansijaa, vaikkakin tällaisia järjestelmiä on jo nykyisinkin käytössä eri autonvalmistajilla. Kuten kuvasta 1 voidaan havaita, on mukautuvan vakionopeudensäätimen rinnalle usein tuotu muita avustinjärjestelmiä käyttämällä samaa sensorijärjestelmää.

Tutkalla mitattaessa auton keulalla oleva lähetin-vastaanotin syöttää eteenpäin radioaaltoja. Aaltojen takaisinheijastumista voidaan laskea edellä ajavan auton etäisyys. Lidar-sensori puolestaan toimii lähettämällä laservalopulssin, jonka takaisinheijastumiseen kuluvan ajan perusteella voidaan määritellä etäisyys edessä olevaan ajoneuvoon. Molemmissa mittaustavoissa on omat etunsa, mutta myös huonoja puolia.

Järjestelmän jatkokehityksessä mukaan on tullut myös kamera, jolla halutaan parantaa järjestelmän luotettavuutta. Nykyisin on jo olemassa myös pelkästään kameraan perustuvia sovelluksia, ja niiden etu tutkalaitteistoihin nähden on selvästi edullisempi hinta. Samaa kameraa voidaan hyödyntää muissa avustinlaitteissa, kuten esimerkiksi jalankulkijan tunnistuksessa, liikennemerkkien tulkinnassa ja kaistavahtisovelluksissa.

Kameran käyttöä pyritään lisäämään sen edullisuuden sekä monikäyttöisyyden vuoksi. Kameralla voidaan toteuttaa monia muitakin avustinjärjestelmiä. Kame-

ratekniikalla toteutetut järjestelmät luokitellaan joko monokulaari- tai stereojärjestelmiin. Monokulaarisessa järjestelmässä käytetään yhtä kameraa, kun taas stereojärjestelmässä on kaksi kameraa. (6.)

Ensimmäisenä pelkästään kameraan pohjautuvan järjestelmän esitteli BMW i3 –mallissaan vuonna 2013. Tällaista järjestelmää kutsutaan nimellä V.O ACC(vision only adaptive cruise control). Järjestelmän on kehittänyt Mobileye-niminen yritys. Järjestelmä ei tarvitse tutka-antureita toimiakseen, vaan se käyttää yhtä kameraa sekä kuvankäsittelyalgoritmeja esteiden tunnistamiseen ja etäisyyden arviointiin. Etäisyys arvioidaan käyttäen puhtaasti näkökulman lakeja. (7.)

Autonvalmistaja Subaru kehitti oman versionsa kamerapohjaisesta laitteesta, jonka tuloksena se esitteli EyeSight-järjestelmänsä vuonna 2015. Subarun järjestelmissä käytetään stereonäköä, eli kahta erillistä kameraa. Näin saadaan etäisyydenmittauksen virhemarginaalia pienemmäksi. Lisäksi kahdella kameralla saadaan etuja muihinkin avustinjärjestelmiin. (8.)

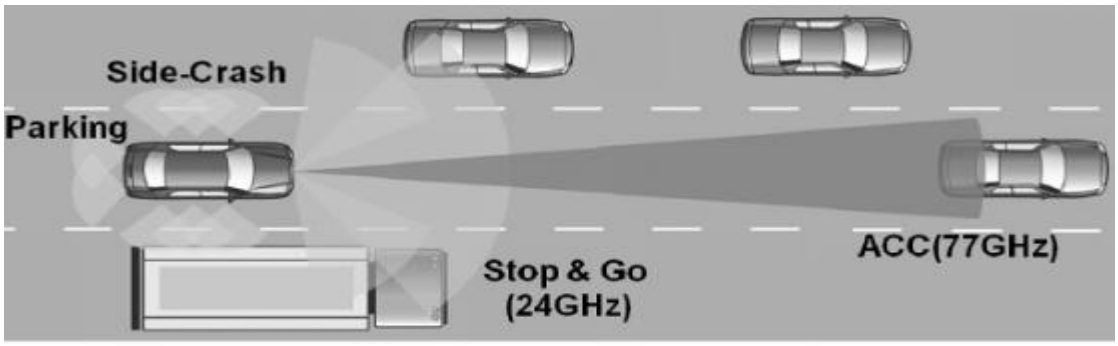
Myös ultraääntä on käytetty joissakin tapauksissa, kuten pysäköintitutkissa, mutta sen käyttöä rajoittaa lyhyt toimintasäde. Niinpä se ei sovellu käytettäväksi suurissa nopeuksissa toimivaan nopeuden- ja etäisyydensäätelyyn.

2.2.1 Radioaaltotutka

Radioaaltoja lähettävä ja heijastumia vastaanottava tutka on aktiivinen mittalaite. Toiminta perustuu siihen, että signaalin kohdatessa esteen osa sen tehosta heijastuu takaisinpäin. Sen mittausetäisyys on täysin riippuvainen käytettävästä taajuudesta. Mitä matalampaa taajuutta käytetään, sitä kauemmas sen kantomatka ylettyy.

Nykyaikainen ajoneuvo sisältää useita eri informaatio- tai avustinjärjestelmiä. Käyttötarkoitusten vaihdellessa tarvitaan myös toiminnaltaan erilaisia tutkalaitteistoja. Esimerkiksi sivutörmäysvaroitin tai pysäköintitutka tarvitsee laajan kulman ja tarkan etäisyystiedon(mittausresoluution), mutta ei niinkään pitkälle ulottuvaa mittausta. Stop & go- järjestelmä hyödyntää keskipitkän kantomatkan tutkaa. Kantama ulottuu 10-40m säteelle. Menetelmällä saadaan kuitenkin suhteellisen laaja havaintokulma, 30-60 astetta. Mukautuva vakionopeudensäädin taas tarvitsee pitkän kantomatkan, mutta havaintokulma voi olla pienempikin. Nämä kolme erityyppistä käytössä olevaa järjestelmää poikkeavat myös modulointitavan perusteella. Luokittelu tehdään yleensä tutkan kantomatkan perusteella.(kuva 2).

Lyhyen matkan tutkat toimivat 24GHz:n taajuudella. Kantomatka on yleensä alle 10 metriä ja niissä käytetään pulssimodulaatiota. Tällainen tutka on käytössä sivutörmäysvaroittimissa ja pysäköintiavustimissa.(9.)



	Freq.	BW	Modulation	Angle	Range	Resolution	Application
Short Range	24GHz	7GHz	Pulsed	70°	10m	< 10cm	Side-Crash Parking
Mid Range	24GHz	250MHz	FMCW	30°~60°	40m	~ 1m	Stop & Go
Long Range	77GHz	1GHz	FMCW	16°	150m	~ 1m	ACC

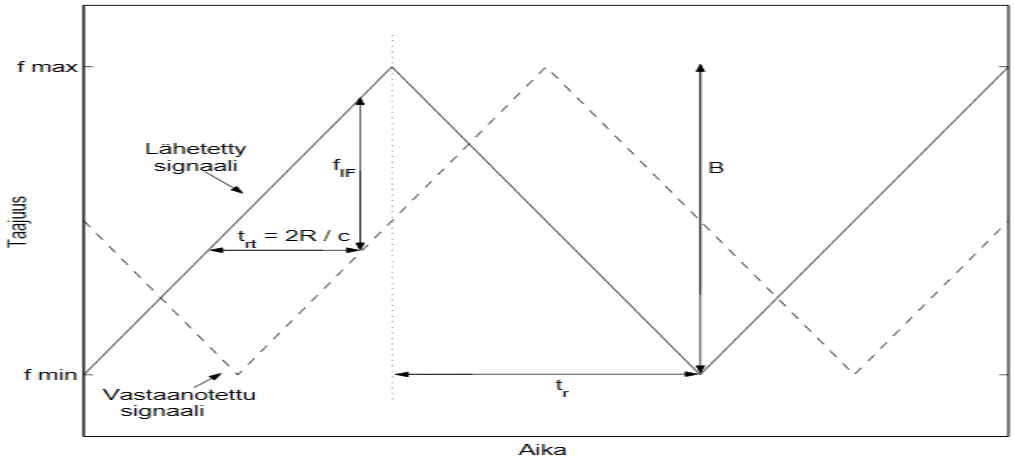
Kuva 2. Ajoneuvon tutkajärjestelmien luokittelu (9.)

Radiotaajuuskaistalta on varattu oma alue maantiekuljetusten ja liikenteen telematiikan tutkalaitteiden käyttöön. Taajuusalue käsittää 76–77GHz:n taajuudet. Tällöin operoidaan ns. millimetriaaltotaajuuksilla. Korkeiden taajuuksien käytöllä on monia etuja. Tekniikkaan soveltuvien antennien kulmaresoluutio on hyvä, komponentit ovat kooltaan kompakteja ja soveltuvat siten hyvin käytettäviksi pienissä tiloissa. Lisäksi korkeat taajuudet ovat elektromagneettisen spektrin ruuhka-alueen ulkopuolella mahdollistaen laajan kaistanleveyden käytön tiedonsiirrossa. (10, 11.)

Eri tarkoituksiin käytetään tekniikaltaan hieman toisistaan poikkeavia ratkaisuita. Laite lähettää signaalia jatkuvasti tai pulsseissa eteenpäin samalla kun se vastaanottaa heijastumia. CW-tutka (Carrier Wave, kantoaaltotutka) lähettää jatkuvaa signaalia eteenpäin. Lähtökohtaisesti sillä ei kuitenkaan voida mitata kohteen etäisyyttä, koska doppler-ilmiön avulla saadaan ainoastaan nopeustieto. Ongelmasta päästään moduloimalla lähtevää signaalia sini-, sahalaita- tai kolmioaallolla, jolloin etäisyys saadaan laskettua signaalien aikaeron avulla. Useimmiten moduloinnissa käytetään jatkuvaa kolmioaaltoa (kuva 3). Tällöin lähetetyn ja vastaanotetun signaalin vaihe-eron avulla voidaan määritellä etäisyys ja sen muutosnopeus. Tällaista tutkaa nimitetään taajuusmoduloiduksi kantoaal-

totutkaksi (FM-CW, Frequency Modulated Carrier Wave). Lähietäisyyden tutkajärjestelmässä on kyseessä pulsseja lähettävä tutka (PD-radar, Pulse Doppler). Takaisinheijastuma poikkeaa lähetetystä signaalista taajuuden perusteella. Tätä erotusta kutsutaan doppler-taajuudeksi. (12, 13.)

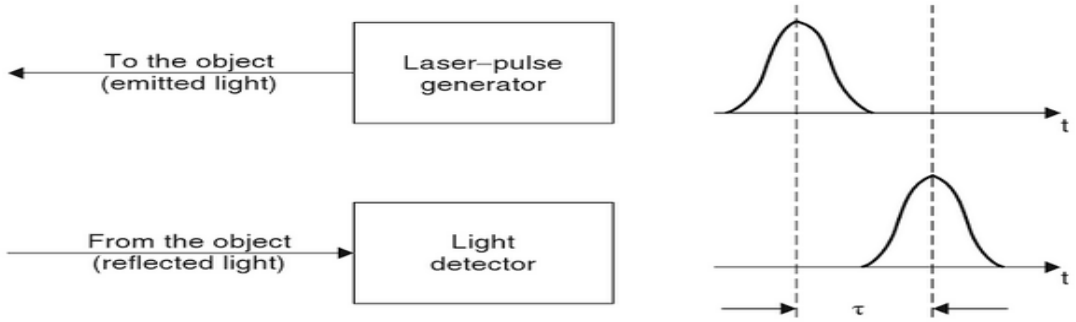
CW-järjestelmien heikkous on niiden korkea hinta. Sen toteutus on monimutkaisempi kuin vastaavan järjestelmän toteutus laser-järjestelmällä (14.)



Kuva 3. FM-CW-tutkissa käytetyn moduloinnin periaate (13.)

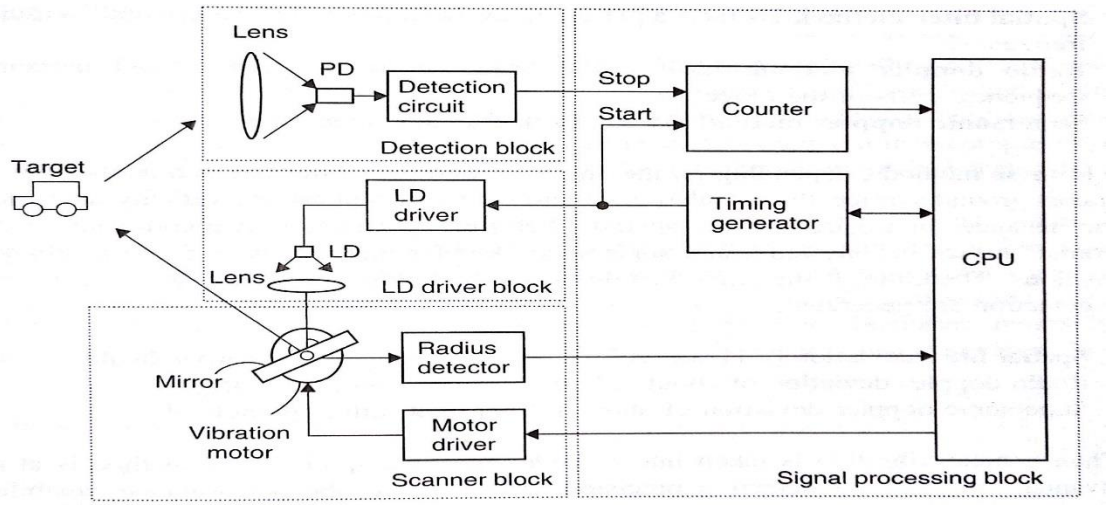
2.2.2 Laservalotutka

Aivan ensimmäiset mukautuvat nopeudensäätelyjärjestelmät toteutettiin hyödyntämällä lidar-tekniikkaa. Se toimii lähettämällä sarjan laservalopulsseja mittauksen kohdetta päin, ja pulssin heijastumien paluuaika mitataan. Tämän tekniikan merkittävimmät edut ovat sen tarjoama mittaustarkkuus sekä edullinen hinta. Lisäksi sen toteutus onnistuu tutkaan verrattuna yksinkertaisemmin. Tällä tekniikalla on kuitenkin vaikeuksia havaita huonosti valoa heijastavia kohteita.(14.)



Kuva 4. Etäisyydenmittaus pulssien aikaeron avulla. (15, s.88.)

Lasertutka koostuu neljästä eri lohkosta (kuva 5). Ne ovat signaalinkäsittely(prosessori), valon lähetys(pulssigeneraattori) ja vastaanotto sekä skanneri. Valon lähetyksen käynnistyessä myös prosessorin laskuri käynnistyy ajan mittausta varten. Lähetys tapahtuu linssin ja peilin avulla. Vastaanotettu signaali muunnetaan sähköiseksi ja vahvistetaan. Mikäli signaalin arvo ylittää määritetyn kynnysarvon, laskuri pysäytetään ja etäisyys lasketaan tämän arvon perusteella (kuva 4). (15, s.89.)



Kuva 5. Lasertutkan lohkokaavio. (15, s.91.)

Kun välimatka tutkan ja mitattavan kohteen välillä kasvaa, vastaanotetun valon määrä pienenee. Jossain vaiheessa valon määrä saavuttaa tasapainopisteen, jossa vastaanottimen kohina on yhtä suuri. Tämän pisteen avulla voidaan määrittää suurin mahdollinen mittaustäisyys. Sääolosuhteet vaikuttavat mittausetäisyyteen olennaisesti. (15, s.89.)

Laservalon aallonpituus on radioaaltotutkaa huomattavasti pienempi. Se on yleensä ajoneuvotekniikan järjestelmissä välillä 600-1000nm. Tällöin puhutaan näkyvän valon ja infrapunavalon alueista. Koska järjestelmä ei keskitä suurta energiaa pienelle alueelle, siitä ei aiheudu vaaraa ympäristölle tai ihmisille. (17.)

2.2.3 Kamerapohjaiset järjestelmät

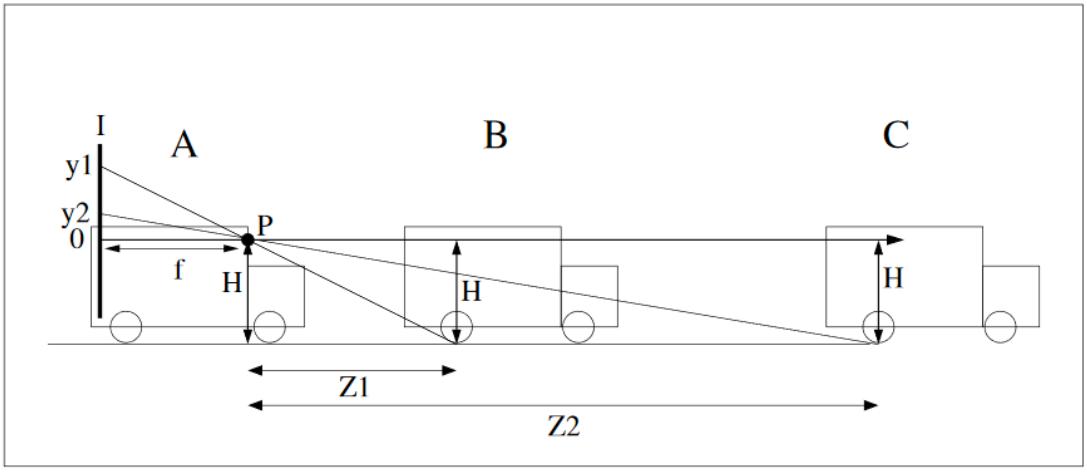
On todistettu, että riittävä tarkkuus turvalliseen toimintaan saavutetaan myös konenäön avulla. Mobileye-niminen yritys kehitti tarvittavan laitteiston ja asensi sen testiautoonsa. Järjestelmä asennettiin tutkalaitteistolla varustettuun ajoneuvoon, mutta tutkan sijasta ohjainyksikkö sai datansa kamerajärjestelmältä. Myös tutkan mittaamat arvot kirjattiin lokitiedostoon vertailua varten. Autoa on testattu tuhansia maileja vaihtelevissa olosuhteissa. Tutkimuksen mukaan jopa VGA-tasoisella yksittäisellä kameralla voidaan näkökulman lakeja hyödyntäen saada tarvittava data avustinjärjestelmiä varten.

Kuvan 6 kaavalla saadaan kohteen korkeus kuvassa laskettua. Kuvassa etäisyydellä Z oleva piste näkyy korkeudella y, kun kameran korkeutta merkitään H:lla. Pieni f-kirjain tarkoittaa kameran polttoväliä. (7.)

$$y = \frac{fH}{Z} \rightarrow \frac{y}{f} = \frac{H}{Z} \rightarrow Z = \frac{fH}{y}$$

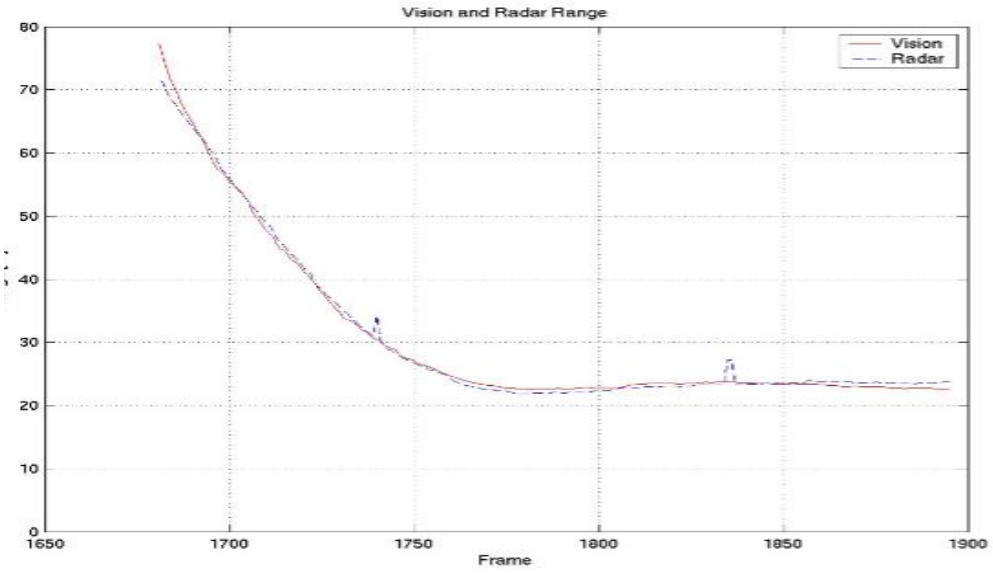
Kuva 6. Kohtauspisteen ja etäisyyden arvioinnissa käytettävä kaava. (7.)

Käytettäessä yllä olevaa kaavaa etäisyyden määrittelemiseksi kameran täytyy pystyä tien ja ajoneuvon kohtauspisteen havaitsemiseen. Sen jälkeen voidaan kaavaa johtamalla laskea ajoneuvon etäisyys. Esimerkkitilanteessa (kuva 7) kamera on sijoitettu ajoneuvoon A korkeudelle H. Ajoneuvon B etäisyyttä merkitään Z1:llä. Tien ja ajoneuvon kohtauspiste projisoituu kuvaustasolle(I)korkeudelle y1. Nämä pisteet muodostavat kaksi yhdenmuotoista kolmiota horisontaalitasoon nähden, joten voidaan johtaa kaava tien ja renkaiden kohtauspisteen laskemiseksi. Lopuksi voidaan laskea ajoneuvon etäisyys.



Kuva 7. Kuvausgeometrian kaavakuva neulanreikäkameralla. (7.)

Verrattaessa laitteistojen mittaustuloksia voidaan havaita, että kamerapohjainen järjestelmä kykenee riittävään tarkkuuteen liikennetilanteissa (kuva 8). Mittaustarkkuutta voidaan vielä tästäkin lisätä stereonäkölaitteistolla, mutta tällöin käytetään erilaisia menetelmiä etäisyksien laskentaan.

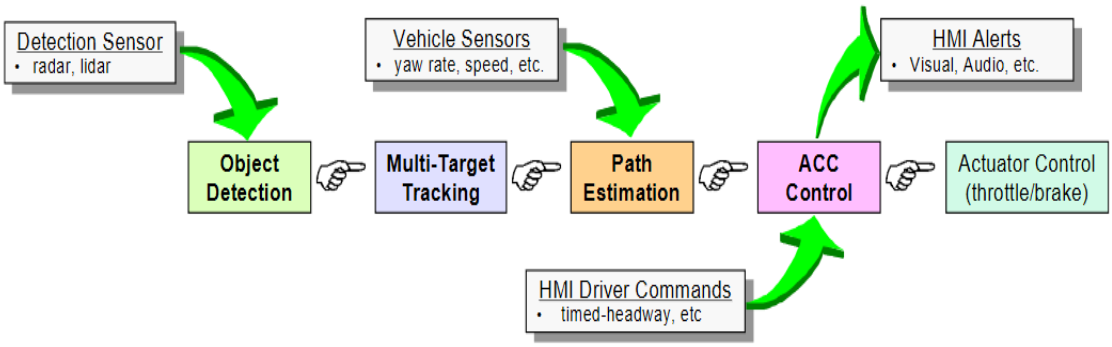


Kuva 8. Tutkajärjestelmän ja kameralaitteiston etäisyysmittausten vertailu.

3 YHTEENVETO

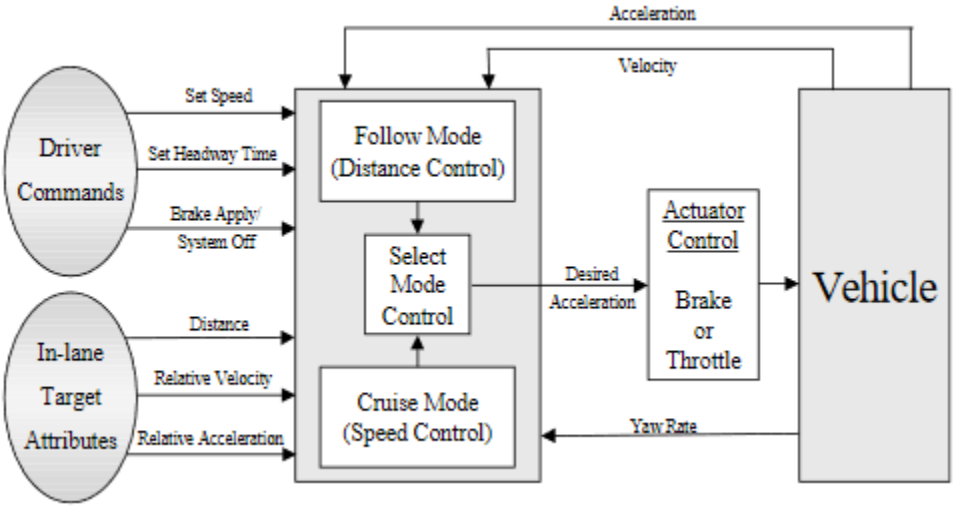
Adaptiivinen vakionopeudensäädin vaatii jonkin verran tekniikkaa ja auton järjestelmien yhteistoimintaa. Loppujen lopuksi sen toimintaperiaate voidaan esittää hyvin yksinkertaisesti (kuva 9). Etäisyyden määrittelyn jälkeen järjestelmän tulee arvioida, onko kyseessä todellinen ajoneuvo. Varsinkin lidar-järjestelmissä tämä muodostuu tärkeäksi, koska se pystyy havaitsemaan todella pieniä kohteita. Seuraavaksi arvioidaan, onko kohde uusi, vai jo aiemmin havaittu ajoneuvo. Etäisyyssensorin havainnot joko sulautetaan aiemmin havaittuun kohteeseen tai muodostetaan uusi kohde. Tämä on mahdollista vertaamalla havainnon nopeutta ja etäisyyttä aiempiin kohteisiin. Ajoneuvon sensoreiden dataa hyödyntäen saadaan selville niin sanottu vaappumisnopeus, eli oman ajoneuvon suunta ja kulma.

Verrattuaan sensoreilta saatuja tietoja keskenään järjestelmä valitsee oikean vaihtoehdon toimintojen joukosta. Se voi olla varoitus ajotietokoneen näytöllä, varoitus äänimerkin avulla tai jopa ajoneuvon itsenäinen pysäyttäminen. Joissakin edistyneissä järjestelmissä on mukana traffic jam assist -toiminto, joka osaa pysäyttää auton liikenteen mukaan, ja kiihdyttää takaisin matkavauhtiin liikenteen sen salliessa. (5, 16.)



Kuva 9. Avustinjärjestelmän toiminta. (16.)

Kuvassa 10 on nähtävissä yksinkertaistettuna ohjainyksiköiden kommunikointi keskenään. Periaatteessa järjestelmässä on kaksi toimintatapaa: se seuraa edellä olevaa ajoneuvoa tai pitää yllä kuljettajan säätämää matkavauhtia. Valinta näiden kahden toimintatavan välillä tapahtuu yhdistämällä tiedot kuljettajan esittämistä käskyistä ja oman sekä muiden ajoneuvojen liikkeistä.



Kuva 10. Järjestelmän toimintatavan valinta. (16.)

Verrattain pienellä hinnalla voidaan minimoida kuljettajasta johtuvia virheitä. Lisäksi järjestelmillä saavutetaan muutakin hyötyä, kuten liikenteen sujuvuutta. Kuolemaan johtaneita onnettomuuksia sekä taloudellisia menetyksiä voidaan merkittävästi vähentää teknologialla, koska laitteisto ei keskity ajon aikana muuhun kuin tehtäväänsä. Tehokkaasti toimiva laitteisto voi havaita asioita, joita tarkkaavaisinkaan kuljettaja ei huomaisi ajoissa. Yhdysvalloissa suoritettujen tutkimusten mukaan jopa 88% peräänajokolareista johtuu kuljettajan huomiointivirheistä tai liian lyhyistä turvaväleistä. (16.)

Järjestelmien kehittyessä kuljettajan rooli ajoneuvon hallinnassa pienenee jatkuvasti tulevien vuosien aikana. Itseohjautuvat autot tekevät tuloaan, mutta niiden lopulliseen läpimurtoon voi vielä kulua aikaa. Turvallisuusominaisuuksien kehityttyä riittävästi ne onnistuvat varmasti houkuttelemaan asiakkaita erityisesti liikkumisen helppouden takia.

LÄHTEET

1. Älyliikenne. Trafi 2016. Saatavissa: http://liikennelabra.fi/alyliikenne/. Hakupäivä 26.2.2016.

2. Self-driving car. Google 2009. Saatavissa: https://www.google.com/selfdrivingcar/how. Hakupäivä 15.2.2016.

3. History of Mitsubishi Motors. Saatavissa: http://www.mitsubishi-motors.com/en/company/history/1990/index.html. Hakupäivä 19.3.2016.

4. Autonomous cruise control system. Wikipedia 2016. Saatavissa: https://en.wikipedia.org/wiki/Autonomous_cruise_control_system. Hakupäivä 19.3.2016.

5. The Development and Application of ACC System. Bian, Ning – Liu, Jifeng – Du, Jiangwei – Guo, Shun – Yang, Yanding – Chen, Ji – Shi, Tingting – Yue, Zhi 2014. Saatavissa: http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=6802788. Hakupäivä 19.3.2016.

6. Stereo-Assist: Top-down Stereo for Driver Assistance Systems. Stein, Gideon – Gdalyahu, Yoram – Shashua, Amnon. Saatavissa: http://www.cs.huji.ac.il/~shashua/papers/StereoAssist-ver5.pdf. Hakupäivä 25.4.2016.

7. Vision-based ACC with a Single Camera: Bounds on Range and Range Rate Accuracy. Stein, Gideon – Ofer, Mano – Shashua, Amnon. Saatavissa: http://www.mobileye.com/wp-content/uploads/2011/09/VisiobBasedACC.pdf. Hakupäivä 25.4.2016.

8. Subaru EyeSight. Saatavissa: http://www.subaru.com/engineering/eyesight.html. Hakupäivä 30.8.2016.

9. A Fully Integrated 77 GHz FCMW Radar Transceiver in 65-nm CMOS Technology. Saatavissa: http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=5610983. Hakupäivä 23.4.2016.

10. Radar equipment operating in the 76 GHz to 77 GHz range. ETSI 2006. Saatavissa : http://www.etsi.org/deliver/etsi_en/301000_301099/30109102/01.03.02_60/en_30109102v010302p.pdf. Hakupäivä 14.4.2016.

11. A millimetric car radar front end for automative cruise control. Robinson, J. – Paul, D.K . – Bird, J. – Dawson, D. – Brown, T. – Spencer, D. – Prime, B. 2002. Saatavissa: http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=668228. Hakupäivä 14.4.2016.

12. Doppler radar. Wikipedia 2016. Saatavissa: https://en.wikipedia.org/wiki/Doppler_radar. Hakupäivä 7.4.2016.

13. Lumen ominaisuuksien mittaus tutkalla. Rinne, Eero 2005. Saatavissa: http://docplayer.fi/719055-Teknillinen-korkeakoulu-sahko-ja-tietoliikennetekniikan-osasto-eero-rinne-lumen-ominaisuuksien-mittaus-tutkalla.html. Hakupäivä 23.4.2016.

14. Adaptive Speed Control for Automotive Systems. Gray, Nicholas 2011. Saatavissa: http://www.ti.com/lit/an/snaa125/snaa125.pdf. Hakupäivä 20.5.2016.

15. Vlacic, Parent, Harashima 2001. Intelligent vehicle technologies: theory and applications. Butterworth-Heinemann.

16. Comparison of Lidar Based and Radar based Adaptive Cruise Control Systems. Saatavissa: http://connectedvehicle.itsa.wikispaces.net/file/view/Comparison+of+Lidar-Based+and+Radar-Based+2000-01-0345.pdf/456154696/Comparison%20of%20Lidar-Based%20and%20Radar-Based%202000-01-0345.pdf. Hakupäivä 27.8.2016.

17. Laserluokat. STUK 2015. Saatavissa: http://www.stuk.fi/aiheet/laserit/laserluokat. Hakupäivä 2.9.2016.

LIITE 2

OULU UNIVERSITY OF APPLIED SCIENCES

Miro Kuusijärvi

MEDICAL APPLICATION DESIGN

MEDICAL APPLICATION DESIGN

Miro Kuusijärvi
Bachelor's Thesis parts 2 and 3
Autumn 2017
Information Technology
Oulu University of Applied Sciences

ABSTRACT

Oulu University of Applied Sciences
Degree Programme in Information Technology, Option of Device and Product Design

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Author: Miro Kuusijärvi
Title of the bachelor's thesis: Medical Application Design
Supervisors: Veijo Väisänen
Term and year of completion: Autumn 2017 Number of pages: 56

The objects of this thesis were to research the regulative requirements for medical software development, to provide requirements and test protocol for StepLab usability tests and to compare gathered information with the current implementation of the application.

The primary reason for the execution of this research was to ensure that the design of the StepLab Application will be established in compliance with the regulations for medical devices thus allowing the product to achieve the certification mark. The commissioner requested concentration on the legislation of European market area, which is the primary target for StepLab.The standard library of the MoveSole Ltd was utilized for gathering the regulative requirements. The best practises of UI evaluation were researched for usability test plan design.

This thesis provides a comprehensive description of requirements for medical UIs. StepLab pilot tests were summarized and proposals for StepLab Application design were suggested. These proposals are likely to be implemented and tested in the future usability tests according to the created test protocol. Subjects of this thesis form a design guideline for medical software development.

Keywords: usability testing, software safety classification, UI

PREFACE

This bachelor's thesis was commissioned by MoveSole Ltd. The work was done during the autumn of 2017. This document is the latter part of a two-part bachelor's thesis.

I would like to thank Sami Puoskari and Jaana Kananen of MoveSole Ltd for their valuable guidance during this thesis work. I am grateful for the opportunities and responsibility that MoveSole Ltd offered me during the final phases of my studies.

This is a shortened version of the original document. Due to confidential nature of subjects related to the StepLab Application, the usability test protocol and some of the UI specific parts of this thesis were omitted from the final report.

Oulu, 12.9.2017
Miro Kuusijärvi

CONTENTS

VOCABULARY

EU	European Union
EEA	European economic area
FMEA	Failure mode and effect analysis
Harm	Physical injury or damage to the health of people, or damage to the property or the environment
Hazard	Potential source of harm
Hazardous situation	Circumstance in which people, property or the environment are exposed to one or more hazards
iOS	Operating system for smart devices from Apple
Manufacturer	Natural or legal person with responsibility for designing, manufacturing, packaging or labelling a medical device
MDD	Medical device directive
MDR	Medical device regulation
MIT	Massachusetts Institute of Technology
SoC	System on chip
SOUP	Software of unknown provenance
UI	User interface

1 INTRODUCTION

Medical device industry in Finland has been a steadily growing field of business for the past few years. The trade surplus in the year 2013 was 700 million euros. In 2016, it already exceeded a milestone of one billion euros. The overall value of exports was over two billion euros. Finland is one of the few countries in the world which is exporting more health technology than importing (25.). Only 1% of the whole production stays inside the Finnish economic area, thus it is necessary to know international legislative requirements (2.). The sales and development of medical devices are controlled by local authorities. For example, the EEA has its own regulations, while in the United States the competent authority is FDA (Food and Drug Administration) with slightly different instructions (4.). The intended use of the device or software determines whether it is a medical device or not. If the product falls in the medical device category, there will be a set of regulations to be considered.

FIGURE 1. StepLab system introduced

MoveSole Ltd is a small or medium-sized enterprise located in Oulu, Finland. The company was founded in 2014. However, the design and development of the product started a few years earlier. The company is developing a cost-effective force measuring device called StepLab. StepLab consists of insoles with the SoC integrated circuit and the StepLab Application run by a smart device (figure 1). The operating system of the smart device is Android. The product is developed for medical professionals to gain information about force distribution during walk. Therefore, it is a medical device, the manufacturing of which is strictly controlled by laws. During the project planning, it became clear that the first step of designing a UI to the medical device is to implement a comprehensive study of regulatory requirements.

In this thesis, the requirements of application design in the European market area are provided. Common usability aspects will be compared to the results of the StepLab pilot usability test results. The usability test protocol for StepLab will also be established. Gathered information will be combined to be the guideline for application design and implementation. Concentration is focused on subjects relevant to the StepLab Application.

2 OVERVIEW OF REGULATIONS AND STANDARDS

2.1 Medical Device Directive

Medical devices in European countries are regulated by European Union directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993)
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)
- Council Directive 2007/47/EC. (1; 2.)

The New Medical Devices Regulation 2017/745 for the European market area was adopted by the EU on April 5, 2017. This will replace the Medical Device Directive and Active Implantable Medical Devices Directive after three years of transition time. (31.) StepLab will be designed and developed in accordance with the old regulation. For this reason, this thesis does not take a stand on the requirements of the new Medical Device Regulation.

The Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices), hereafter referred to as MDD, is regulated to harmonize the legislation in the European market area. It is revised with the Directive 2007/47/EC. The MDD defines requirements for essential performance and safety which must be complied with to sell a product as a medical device in European countries.

The article 1 of MDD gives a definition of a medical device. All devices or software which are used to

- diagnose, prevent, monitor, treat or alleviate a disease,
- diagnose, monitor, treat, alleviate or compensate an injury or a handicap,
- investigate, replace or modify of the anatomy or a physiological process or
- control conception

falls in the category of a medical device.
The article 3 states that devices must comply the essential requirements given in the Annex 1 considering their intended use. The conformity with the MDD is achieved by meeting the requirements of harmonized standards. A reference to standards is stated in the article 5. (2.)
Devices must be classified according to the article 9. There are four different classes (I, IIa, IIb and III). The classification must be done by the rules given in the Annex IX.
The article 11 of MDD covers the requirements of conformity assessment procedure. Depending on the class of the device the manufacturer must follow some of the procedures set out in Annexes II, IV, V or VI. The class of the device also determines whether a certified quality management system is mandatory or not. It is crucial to establish a link between device classification and the appropriate Annex to be used.

2.2 Harmonized standards

A successful design and production of a medical device requires a quality management system (3, p.14). ISO 13485 – Quality management systems – Requirements for regulatory purposes (6.) is on a European harmonized standards list, thus the system must be based on it. Figure 2 represents an overview of main process areas of this standard. A process approach and precise documentation of processes and procedures are required to achieve compliance with this standard (3, p.14).

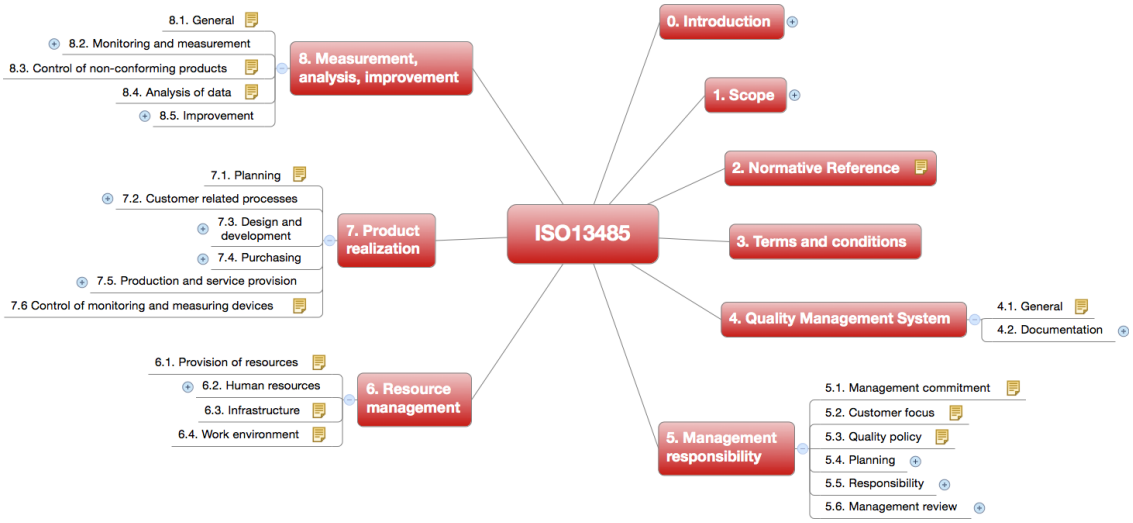

FIGURE 2. An overview of the standard ISO 13485 (11.)

This standard can be applied by multiple different ways. The manufacturer can

- establish a full quality assurance system, which is suitable for all medical devices and obligatory for high risk level products,
- establish a production quality assurance system which is applicable for lower risk level products or
- establish a product quality assurance system, which is suitable only for the lowest risk level products.

It is recommended to create a complete quality management system (3, p.14). With a quality management system, the manufacturer can demonstrate its ability to produce medical devices which provide adequate safety and meets the regulative requirements. The standard requires the manufacturer to document all exceptions, due to regulations or device nature, to a quality management system description documentation (3, p.15). Guidance for applying a quality management system to software development can be found in ISO/IEC 90003. As stated in IEC 62304, this guidance is not mandatory but highly recommended (9.).

Risk management guides and supervises product design and company operations. Risk management can be integrated into the operation process, or it can

construct a separate process. However, it must contain some basic elements to identify and improve weaknesses of a production (3, p.35). The standard ISO 14971 defines requirements for risk management activities. It specifies a process to identify hazards regarding medical devices, to estimate and evaluate risks and to monitor risk controls (5.). The standard for software life-cycle processes (6.) includes some additional risk management requirements considering software development.

The software of the medical device is closely related to safety therefore it must have high integrity (9.). IEC 62304 (software standard) is applicable for software development activities. The software standard gives the manufacturer a framework which covers software life cycle activities altogether. Common requirements to be used in software development are introduced without any certain life cycle model. The software standard is applicable for general Waterfall methods as well as Agile methods (18.). It does not define an exact way of getting things done, but it provides a framework to verify that all the necessary steps in the standard have been taken. The standard presumes that the manufacturer has already established a quality management system including risk management activities. It aims to benefit manufacturers by

- defining a minimal set of processes for software life-cycle,
- allowing processes to be chosen flexibly,
- permitting software partition into items and
- being harmonized by the EU. (9.)

The requirements of this standard are depended on the software safety classification. Applying the software standard in practise means that a quality management system must include a risk management process. The risk management process must cover the whole life cycle of devices. In other words, the risk management actions described in the software standard amplify the risk management process to cover software specific actions. It is harmonized by EU and recognized by the FDA thus this standard benchmarks software development for both market areas. (18.)

Devices, which are intended to be used in the home use environment, must comply with the standard IEC 60601-1-11 (home use standard). It specifies additional requirements considering especially different use environments.

Patient's safety is related to the ability of the operator to correctly discern the differences between alarm signals. The requirements for alarm systems are defined in the standard SFS-EN 60601-1-8 (alarm standard). It is developed utilizing contributions of medical professionals, engineers and psychologists.

Usability design aims to an efficient, safe and easy to use medical device (3, p.38.). ISO 62366 (usability standard) is the primary standard for medical device usability. The process described in the standard aims to identify and minimize use errors and use-related risks. In other words, its main purpose is to optimize medical devices usability when it relates to safety, efficiency and user satisfaction.

3 REQUIREMENTS FOR SOFTWARE DEVELOPMENT

The software standard provides means for developing safety critical and high reliability software which is suitable for medical devices. The requirements of the MDD are difficult to comply without applying methods of this standard on software development. While this standard is adopted internationally, there is no opportunity for rudimentary software development processes. This also means that quality expectations between Europe and the United States are equalized. (16.)

3.1 Safety classification

Depending on a harm or risk that a software system can cause to a patient, operator or other person, it must be assigned with a safety class. This procedure is described in figure 3. The risk associated with the software acts as an input to the software safety classification. Processes in software standard to be applied are determined by this classification (7, p.9.). Safety classes are defined as follows:

- Class A: no possibility of injury, a few requirements of the standard applicable.
- Class B: no possibility of serious injury, most of requirements of the standard applicable.
- Class C: serious injury or death possible, all the requirements of the standard applicable. (12.)

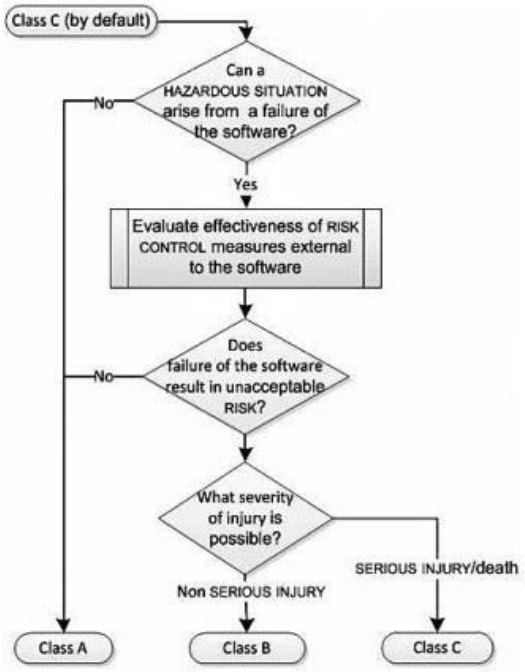

FIGURE 3. Principle for defining a software safety class (7, p.16.)

Serious injury means an injury or an illness which

a) is life threatening,
b) results in permanent impairment of a body function or permanent damage to a body structure, or
c) necessitates medical or surgical intervention to prevent permanent impairment of a body function or a permanent damage to a body structure. (7 p.16; 9.)

The Class A is assigned if the software system does not contribute to a hazardous situation or if a hazardous situation does not result to an unacceptable risk. The Class C is assigned for systems which can contribute to a hazardous situation with an unacceptable risk, for example a serious injury. The software safety class must be documented in a risk management file. Until a safety class is assigned, the manufacturer must apply the Class C requirements for the software system. (4; 7 p.16-17; 9.) Table 1 describes the effects of the safety classification on the required documentation of the software process.

TABLE 1. Effects of the safety classification on the documentation of the software (16.)

Software Documentation	Class A	Class B	Class C
Software development plan	Must contain contents to sections 5.1 IEC 62304:2006. The plan's content list increases as the class increases, but a plan is required for all classes.		
Software requirements specification	Software requirements specification conforming to 5.2 IEC 62304:2006. The content list for the software requirements specification increases as the class increases, but a document is required for all classes.		
Software architecture	Not required.	Software architecture to 5.3 IEC 62304:2006. Refined to software unit level for Class C.	
Software detailed design	Not required.		Document detailed design for software units. (5.4).
Software unit implementation	All units are implemented, documented and source controlled (5.5.1).		
Software unit verification	Not required.	Define process, tests and acceptance criteria (5.5.2, 5.5.3). Carry out verification (5.5.5)	Define additional tests and acceptance criteria (5.5.2, 5.5.3, 5.5.4). Carry out verification (5.5.5).
Software integration and integration testing	Not required.	Integration testing to 5.6 IEC 62304:2006.	
Software system testing	Not required.	System testing to 5.7 IEC 62304:2006.	
Software release	Document the version of the software product that is being released (5.8.4).	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	

3.2 Development process

Developing medical software requires the manufacturer to establish and document a software life-cycle model. Life-cycle model typically starts with development planning and ends with validation of the software. Box numbers in figure 4 are relating to clauses in the software standard. It defines characteristics of every phase including their documentation requirements. Risk management actions should be integrated in the design through the development process. The software standard describes a couple of supporting processes for software life cycle. These are configuration management, risk management and maintenance process. (3, p.41-43; 9.)

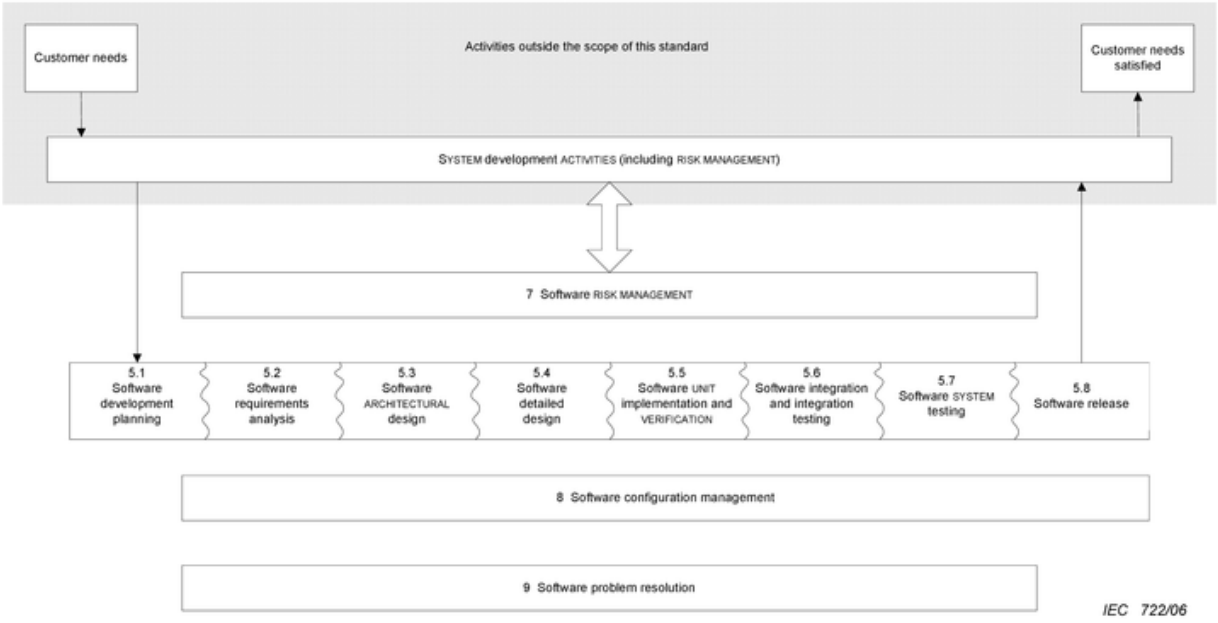

FIGURE 4. An overview of software development activities required by standard ISO 62304 (9.)

3.2.1 Development plan

A software development plan is required to express how the manufacturer conducts activities of the software development process defined in the software standard. The main reason for planning is to reduce risks caused by software. This plan must describe the following things:

- Processes used in the development.
- Deliverables and documentation of activities (information on all software related documentation).
- Traceability between requirements, tests and risk control measures.
- Configuration and change management.
- Problem resolution process for problems detected during the software life-cycle.

The software development plan takes a stand on software integration, verification, tools and consideration of software defects, too. The manufacturer must update the plan as appropriate. (7, p.18-20.)

3.2.2 Requirements analysis & specification

The requirements specification is an important phase of designing software. As shown in figure 5, it is also the most challenging part of it. Majority of the errors occurring in the software are related to a poor or lacking specification. (13.) A key to a flawless specification is to have the right personnel defining the requirements of the software (14.).

Contents of the requirements must include, for example, functional and capability requirements, regulatory requirements and some requirements considering user-interface. When software requirements are established, a re-evaluation of risk analysis is necessary. At the end of this activity, software requirements must be verified and documented. (7, p.21-22.)

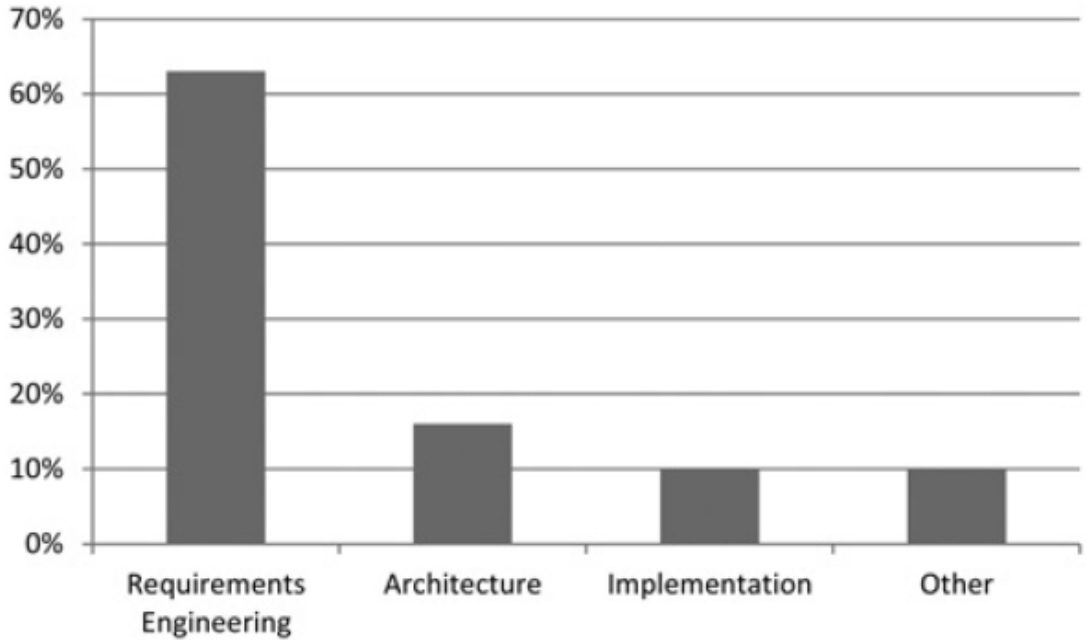

FIGURE 5. The most difficult processes in software projects (15.)

3.2.3 Design

Architectural and detailed design are described in the software standard. Architectural design means that the manufacturer transforms documented requirements to software items in the design. It defines modules and their way to communicate with each other (interfaces) (15.). Architectural design is not finished until all requirements are defined as structural components and their responsibilities are identified. The components relating to the essential performance and safety must be described in the specification (15.). At the end of this activity, it is necessary to verify that the created architecture implements the requirements, supports the interfaces between software and hardware and supports the software of unknown provenance items (7, p.23.). The architecture can change during the software development. In that case, risks caused by changes need to be evaluated using a risk management process (4.).

Items need to be divided into units before transferring the architecture into source code. This is called detailed design. The interfaces between software units and external components must be designed in adequate detail to enable their correct implementation. (7, p.23.)

3.2.4 Implementation

The implementation phase produces source code from detailed design. It is recommended to use coding standards during the implementation to achieve a desired style. Coding standards describe, for example, the requirements for understandability, the restrictions and rules for language usage. After the implementation of software units is done, the manufacturer must verify their functionality and document the results. The documentation must include acceptance criteria for integrating the units into larger software items. (7, p.24.)

3.2.5 System integration and testing

System integration means bringing separately tested components of the code together as a working entity. Integration must be done according to the development plan. It is stated in the software standard that the manufacturer must conduct and document the integration test to address the intended operation of the software. Integration tests and system tests are described as separate actions, but it is acceptable to combine these two to a single set of activities. The evaluation of integration test procedures and regression tests is required. (7, p.25.)

The documentation must support the repeatability of the tests. Test procedures, test results, a software version, hardware and software configurations, test tools, a date and a tester’s identity must be recorded. (7, p.25.) If integration testing reveals any anomalies, the problem resolution process must be applied to them. (7, p.26.)

3.2.6 Release

Before releasing the software, all the verification tasks must be accomplished. The release documentation must contain

- known residual anomalies,
- released version and
- information about the software creation.

The manufacturer must ensure that activities of the software development plan are completed. The released software and its documentation must be archived and retained for the life time of medical device software. A reliable delivery of the software release must be secured. (7, p.27.)

3.3 Supporting processes

3.3.1 Maintenance

The software maintenance process, which is demonstrated in figure 6, seems very similar compared to the development process. However, their purposes differ from each other. The software maintenance process enables the manufacturer to use a smaller process to implement rapid changes into the software. This is beneficial when responding to urgent problems. (7, p.51.)

The software maintenance plan determines how the manufacturer handles feedback and delivers a solution to detected problems. The plan should address how risk management, configuration management and problem resolution processes are used in the maintenance phase. It should also take notice of evaluating and implementing SOUP upgrades, bug fixes and obsolescence. (7, p.28.)

The evaluation of received feedback is required. If it reveals an existence of problem in the software, the manufacturer must document it to the problem report. If the problem is affecting the safety of the medical device, the problem resolution process must be applied to address required changes. Modifications can be implemented using the change control process after the analysis and approval of change request. (7, p.29.)

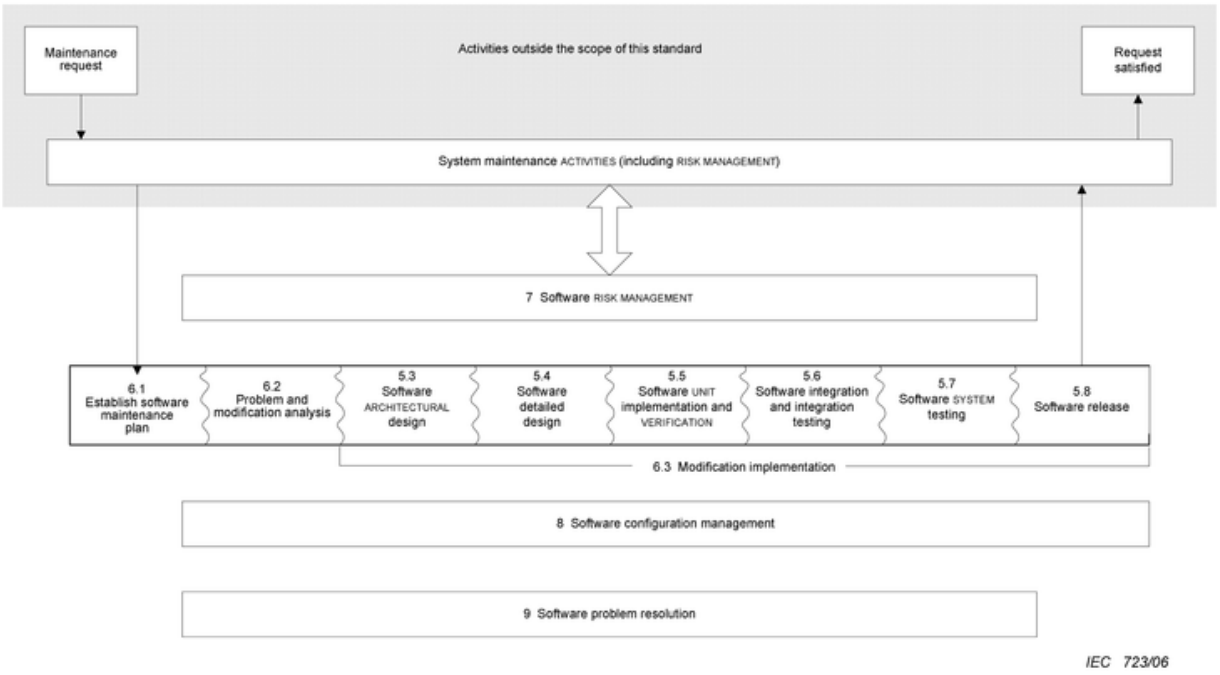

FIGURE 6. An overview of the software maintenance process (9.)

3.3.2 Risk management

The software risk management process identifies software items which could contribute to a hazardous situation defined in the product risk analysis phase. Potential causes of the situation need to be identified and documented. Published SOUP anomaly lists need to be evaluated. (7, p.30.)

Risk control measures need to be defined for all cases documented in the risk management file where a software item can contribute to a hazardous situation. Verification of such measures is necessary. The manufacturer must document traceability between

- a hazardous situation and a software item,
- a software item and a software cause,
- a software cause and a risk control measure and
- a risk control measure and a verification of it. (7, p.30-31.)

When changes to the software system need to be applied, the manufacturer must analyse whether new potential causes to hazardous situations are introduced or new risk control measures are required.

3.3.3 Configuration management

The configuration management process includes controlling of changes, releases of items, change requests of the software and all documentation related to them. The process consists of

- configuration identification,
- change control and
- configuration status accounting. (7, p.32.)

Identification describes configuration items and their versions. If software of unknown provenance is used, its title, manufacturer and unique SOUP designator must be documented. (7, p.32.)

The manufacturer must control changes of the software configuration items. This means documenting information related to change requests and their disposition. In other words, this activity prevents any unauthorized or unintended changes to the software. (7, p.54.) Configuration management must have a verification action for changes. Any invalidated verification caused by change must be repeated. The manufacturer must retain traceability for change. That means documentation of relationship between change requests, problem reports and approval of change requests. The history of system configuration including configuration items must be documented and retrievable. (7, p.32-33.)

3.3.4 Problem resolution

The activities of the problem resolution process are described in figure 7. This process must be applied to all detected defects. Every software based problem must produce a problem report. Problem reports are usually based on the customer's feedback. It describes criticality and other assisting information for solving the problem. The causes of the problem must be investigated and safety aspects must be evaluated with the risk management process. Finally, a change request must be created to solve the problem. If the manufacturer decides that no action is required, rationale for such a decision must be documented. The manufacturer defines parties to be advised after investigation. The risk management file must be updated if necessary. (7, p.33-34.)

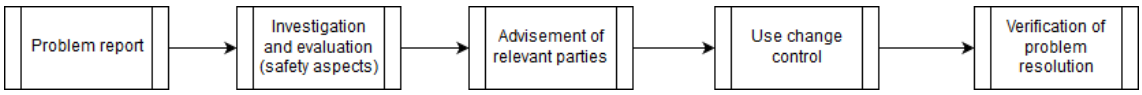

FIGURE 7. Problem resolution tasks introduced.

The change control process must be applied to implement modifications. The verification phase includes writing documentation of test results. These must contain

- results,
- anomalies,
- tested software version,
- configuration of software and hardware,
- date,
- test tools and
- tester identification. (7, p.34.)

4 REQUIREMENTS FOR HOME USE

4.1 Indication of power source state

When a medical device is intended to be used in the home environment, designers must pay attention to some specific details related to the UI. If the device is operated by an internal power source, for example a battery, its state must be indicated. It may be shown continuously or by action of the operator. The state can be indicated as

- number of remaining procedures,
- remaining operating time,
- percentage of remaining operating time or energy or
- fuel cauge. (21, p.24.)

The best option for indicating the remaining energy is measuring it either by the percentage of energy or with a fuel cauge meter. This is because it might be difficult to determine the exact time of operation on a battery-operated device. To avoid data loss during measurements, it is recommended that the battery status should be shown continuously. When the battery level of the smart device is low, necessary information for the operator is required.

4.2 Alarm systems in the home use environment

Every high or medium prioritized alarm condition must produce either auditory or verbal alarm signal. (21, p.30.) If the volume of the alarm system can be lowered below an audible level, the inactivation state must be indicated to the user. (21, p.50.) Other requirements for alarm systems are provided in the Alarm standard and described in the next chapter of this thesis.

5 REQUIREMENTS FOR ALARM SYSTEMS

An overview of the alarm system shall be provided within instructions for use. Documentation must provide a description of all possible physiological or technical alarm conditions assigned with their priorities. (22, p.14.) An alarm condition means a situation in which the device has noticed an existence of a potential hazard.

5.1 Visual alarm signals

A visual alarm signal must always be generated when the presence of any alarm condition is detected. The use environment may require a generation of additional alarm signals. (22, p.16.) For example, it can be distractive and thus demand an auditory or a vibratory alarm signal, too.

In case that a visual alarm signal is indicating a requirement to identify a part of the system, which needs an operator awareness or response, the signal must indicate the highest priority alarm condition and it must be perceivable from 4 meters. (22, p.16.)

The Alarm standard provides two requirements for visual alarm signals:

- The existence and priority of an alarm condition must be correctly perceivable from a distance of 4 meters.
- The visual alarm signal, which indicates a specific alarm condition and its priority, must be legible from at least 1 meter or from the position of the operator. (22, p.38.)

These requirements can be implemented with one signal that complies both requirements or with two separate alarm signals. Accepted symbols are described in the IEC 60417-5307 standard. Priority can be marked, for example, with exclamation marks. In case of multiple alarm conditions occurring simultaneously, every individual alarm must be indicated visually. (22, p.17.)

5.2 Auditory alarm signals

If the alarm system provides auditory signals, one of those must be priority encoded and it must meet requirements for frequency, amplitude differences and duration defined in the standard. It must be generated with a different technology, for example with a voice synthetization. (22, p.17-18.)

Approved alarm sounds are presented in the Alarm standard. If approved alarm sounds are not used, validation by usability testing is required. (22, p.44.) Designers must ensure that the melody used in the alarm signal cannot be confused with signals presented in table 3, 4 and Annex F of the Alarm standard unless their meaning is the same. Auditory alarm signals must be validated in clinical usability tests. (22, p.19.)

The Alarm standard requires an application with a 200-5000 Hz frequency range for auditory alarm signals. The frequency band must differ from most intense background frequencies in the expected environment for use. (22, p.71.)

5.3 Information signals

A visual informative signal must be separable from visual alarm signals at 1 meter. Auditory informative signals must be distinguishable from auditory alarm signals. Their characteristics must be described in the use instructions of the medical device. (22, p.17.)

5.4 Alarm limits

An alarm limit setting can be adjustable, non-adjustable or determined algorithmically. Adjustable alarm limits must be indicated either continuously or by action of the operator. Adjusting alarm limits cannot have an influence on the operation of the alarm system. (22, p.24-25.)

The application must provide means to disable the generation of alarm signals. This inactivation may apply to

- an individual alarm signal,
- a group of alarm conditions or
- an entire alarm system. (22, p.25.)

6 REQUIREMENTS FOR USABILITY

The usability standard requires an application with a user-centred design process, which is called usability engineering (human factors engineering). This process helps the manufacturer to anticipate possible usability problems, to solve existing problems and to provide a better customer satisfaction (24, p.3.). The risk of poor usability must be assessed in the risk management file. The expected output of the process is a better product.

The usability engineering process described in the standard consists of nine stages:

- Preparation of use specification.
- Identification of UI characteristics related to safety and possible use errors.
- Identification of known or foreseeable hazards and hazardous situations.
- Identification and description of hazard-related use scenarios.
- Selection of hazard-related use-scenarios for summative evaluation.
- Establishment of UI specification.
- Establishment of UI evaluation plan.
- Implementation and verification of the UI.
- Validation of the UI. (8, p.14-19.)

To comply with the standards requirements, the manufacturer must document outputs of this process in the Usability Engineering File. Records and documents of the file can form parts of other documentation.

This document demonstrates that the manufacturer has applied usability engineering process activities. This enables an efficient auditing of the development process. The compliance with the Usability standard is checked by inspecting the usability engineering file, therefore it is very important to do it carefully. Table 2 represents documents which must be included in the usability engineering file.

TABLE 2. Documentation requirements of the Usability standard and relationship to risk management

Clause	Documentation requirements	Relationship to ISO 14971
5.1	Use specification • Intended medical indication • Intended patient population • Intended part of the body to be interacted with • Intended user profile • Use environment • Operating principle	Clause 4.2: An input to definition of intended use
5.2	UI characteristics related to safety and potential use errors	Clause 4.2: An input to identification of characteristics related to safety
5.3	Foreseeable hazards and hazardous situations	Clause 4.3, 4.4: An input to the identification of hazards and sequences of events leading to hazardous situations
5.4	Foreseeable hazard-related use scenarios	Clause 4.4: Identified sequences of events leading to hazardous situations acts as inputs to defining hazard-related use scenarios
5.5	Selected hazard-related use scenarios for summative evaluation including rationale for its use and results of applying it	
5.6	UI specification	
5.7	UI evaluation plan including both formative and summative evaluation	Summative evaluation proves that the residual risk relating to the usability of the device is acceptable

It is stated in the standard that use-related risks must be reduced as low as possible. The options listed by their priority are

- inherent safety by design,
- protective measures in the medical device itself or in the manufacturing process and
- information for safety. (8, p.13.)

6.1 Definition of usability

Usability as a term can mean many different things. When talking about medical devices, it is constantly related to safety and efficiency. Traditionally, it is associated with attributes which are learnability, efficiency, memorability, errors and satisfaction. With these attributes the usability of the device can be improved, measured and evaluated. As demonstrated in the figure 8, usability is just a narrow part of overall system acceptability. That defines whether it satisfies all the requirements of the users or not. (20, p.26-28.)

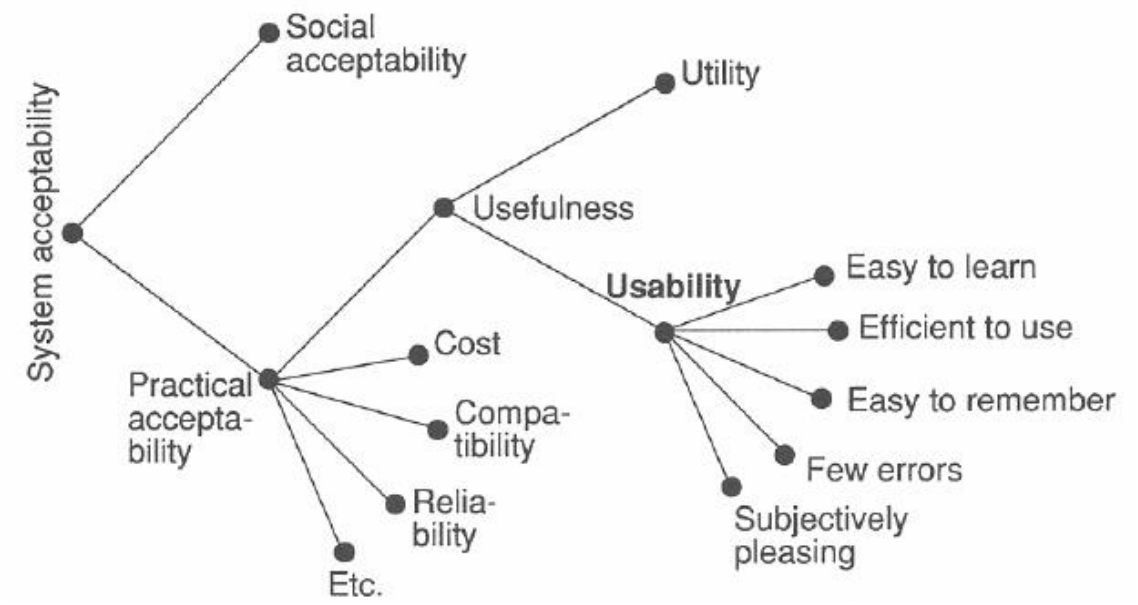

FIGURE 8. A model of the attributes of system acceptability. (20, p.25.)

6.2 Contents of a usability engineering file

6.2.1 Use specification

The most important characteristics related to the use of the medical device must be identified and documented to a use specification. The contents of the specification are inputs to identification of hazards and hazardous situations considering the UI.

The use specification must notice

- intended medical indication,
- intended user profile,
- use environment and
- operating principle. (8, p.14.)

The intended medical indication describes a purpose of the medical device. This information is also required in the accompanying documentation of the device.

The intended user profile consists of factors which could affect the use of the medical device. For example, age, cultural background and possible disabilities are things that should be considered.

The use environment describes places where the medical device is designed to be used. This clause also defines some general concernments such as noise levels, protective equipment required by users and ambient lighting.

The operating principle describes in detail how the medical device achieves its defined intended use. This includes mechanisms by which it also works.

6.2.2 Hazard-related characteristics, situations and use scenarios

The characteristics of the UI, which are safety-related, must be documented. Considering the use specification, UIs of similar medical devices and identified use errors, the manufacturer must identify and store foreseeable hazards and

hazardous situations. During the identification of things above, abnormal use conditions might be found at the same time.

Use scenarios related to hazards and hazardous situations must be identified and documented. These consist of detailed tasks and sequences including the severity of a harm associated with them. The manufacturer must prioritize and choose the most important scenarios for a summative evaluation.

6.2.3 UI specification

Specifying technical requirements of the UI helps the manufacturer to ensure that the medical device risks caused by usability problems are acceptable. The requirements are based on the use specification, use errors and hazardous use scenarios. These may e.g. include display colours and placement of the controls. This specification also contains information on whether specific training or accompanying documentation is needed.

6.2.4 Evaluation of UI

The usability standard requires the manufacturer to establish an evaluation plan for the UI. The plan consists of a formative and summative evaluation. While planning the summative evaluation, the manufacturer must define the acceptance criteria for tasks which the user conducts during usability tests. These criteria must comply with the risk acceptability defined by the manufacturer. Planning ends when the formative evaluation has been completed.

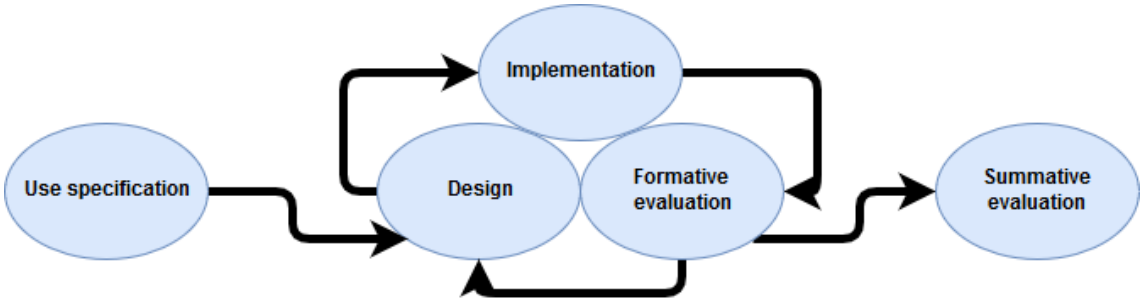

FIGURE 9. UI evaluation cycle described

The UI of the medical device can be tested several times during the development process. Possible usability difficulties and flaws are documented and actions to remove them are taken. The formative evaluation continues until the manufacturer is sure that the final acceptance criteria for the UI validation process will be met (figure 9). Unlike the summative evaluation, the formative evaluation does not have any formal acceptance criteria. (8, p.35.) Described in short, formative usability testing is an evaluation of an evolving design, the purpose of which is to identify potential improvements of the UI. With the formative evaluation, the manufacturer ensures that the design is developing to the right direction. (27, p.90.)

The summative evaluation of the UI can be conducted after the implementation has been finished and adequate quality level reached. Every hazard-related use scenario must be evaluated because the main purpose of this phase is to generate an objective evidence that the medical device can be used safely. As stated in the Usability standard, a failure at this phase means that designers must return to formative evaluation. (8, p.37.) Summative usability testing is an evaluation of production-equivalent design, validating that it fulfils user requirements and that it enables a safe and effective use of the device. (27, p.90.) An appropriately performed summative evaluation reveals quickly if the product is complying with the needs of the user (19.). If the usability of the medical device meets the criteria defined at the evaluation plan, the residual risks related to it are controlled to the acceptable level. (8, p.28-29.)

7 CONSIDERATIONS FOR APPLICATION DESIGN

7.1 Users

The first step of design is to study the intended use (this includes both the intended and unintended use) and users of the product (23, p.4.). When defining the concept of user, it must be kept in mind that everyone whose daily tasks are affected by the device is included. The most basic guideline to improve usability is to “know the user”. (20, p.73.)

7.1.1 User types

Unlike normal commercial products, it is easy to identify users of the medical device as concrete individuals. The highest-level categorization is to divide user groups into medical professionals and patients. The knowledge of user’s age, work experience and educational level is helpful to determine the complexity of the UI. However, it would be wise for the design team to visit the customer site to have a vision of how the device will be used. (20, p.73-75.)

Referring to regulative requirements, intended users and use cases must be documented. Inputs to these can be gathered through the specification, but more detailed information may be needed. The design of the UI should always concentrate on the requirements of the user. Therefore, a comprehensive study of users, their job description and other relevant preferences is recommended. If some of the intended user groups are ignored, there will be a struggle in the product usage. In the worst case, this can lead to an adverse outcome through use errors (23, p.3.). A necessary part of successful design is a multidisciplinary team to provide different aspects related to design (8.).

7.1.2 Common disabilities

Possible limitations or disabilities of the users must be considered, especially if the product is designed for home use. Users may suffer from disabilities such as mobility problems or cognitive problems. Therefore, a home healthcare prod-

uct requires a slightly different approach what comes to the design and development phase (23, p.233.). An entirely different set of factors need to be assessed. Inclusive design, which is sometimes referred to as universal design, means that the device is easy enough for anyone to use. (23, p.227-228.)

For example, a user suffering from monochromatism would find a colorized UI difficult to understand if it is not considered in the design. This problem can be solved by adding an alternate expression of data, such as a numeric or another graphical implementation. The effectivity of the information that requires user interaction can be amplified with vibration.

7.2 Use environment

Understanding the intended use environment of the medical device is as important as knowing the details of the user. These are the factors that cannot be separated when designing a useful and usable medical device. (30.)

Clinical environments provide a certain level of consistency. All the factors may not be identical, but there will be enough similarities for targeting and refining the medical device. For example, space, ambient lighting and noise levels can vary between clinics but they are considered to be suitable for medical operations. (30.)

At the clinical environment, other devices and people will cause many kinds of distractions. When the device requires the operator’s attention, information provided cannot give a possibility for misunderstanding. If audible alarm signals are used, attention must be paid to their volume levels and distinctness. Noise levels are higher than in the designer’s peaceful office. The same goes the other way around, because the medical device must be designed so that it does not distract other critical devices around it. (30.)

Designers can consider home use environments as a worst-case scenario. The unpredictability of the environment combined with the poor usability of the device are serious threats in the home use environment. The manufacturer can try to avoid these problems by examining the most severe home conditions and by ensuring that instructions for use are comprehensive. (30.)

7.3 UI characteristics

Sometimes medical device companies spend months on developing a solution which does not satisfy expectations. This happens especially if some other manufacturer has already brought its product with better usability to markets. The UI can be enhanced with a little investment in human factors engineering even after the first implementation has been done. (23, p.151.)

The aspects of the UI must be considered carefully, because the operator of the medical device does not want to use any extra time to execute the intended task. Every detail in the UI must match as natural way of conducting tasks as possible. Adding a new item or function onto the screen means one more possibility to confuse the user. The best practise is to present only the information the user needs at the exact place and time required. (20, p.115-116.) The principles presented in this chapter help reducing UI related errors and therefore increasing the patient safety.

7.3.1 Navigation

It is normal that users do not want to read instructions to be able to navigate through the UI. Depending on the complexity of the UI, this increases the possibility that the user becomes lost in the application hierarchy. Therefore, components of navigation must be consistent and as simple as possible. Familiar icons such as a home button, do not require a further explanation to understand their meaning. Figure 10 demonstrates how a closable navigation drawer improves the usability of the UI. (28.)

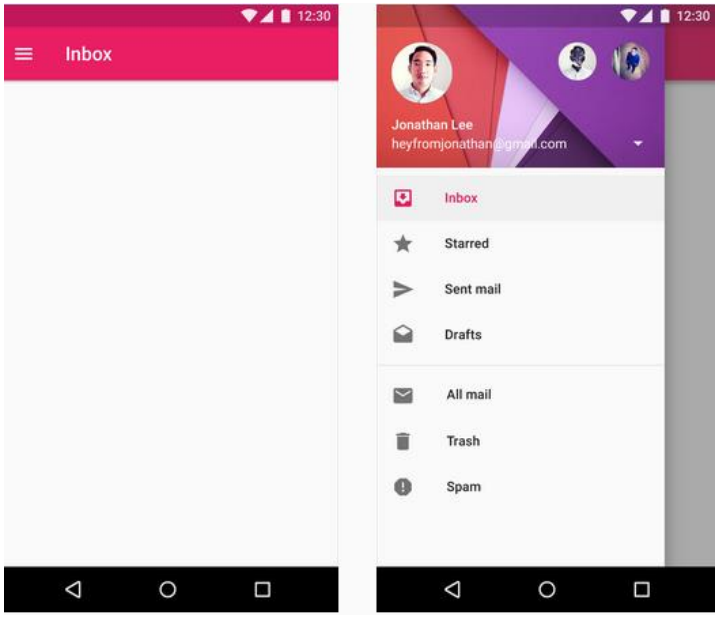

FIGURE 10. Example of an Android navigation drawer (32.)

Providing navigation hints on the screen is very helpful. This includes placing meaningful titles onto screens and subcomponents and grouping navigation components to a single consistent location. It provides an easy way to return to the previous screen or undo an unwanted action without the fear of getting lost or causing harm to a patient. (23, p.152.)

It is recommended to keep the following rules in mind when designing the navigation for the UI:

- Use common elements.
- Keep navigation visible all the time.
- Try to minimize required touches (note that this can reduce the consistent behaviour of the application).
- Use visual hierarchy (figure 11). (28.)

7.3.2 Buttons and icons

The buttons and graphical icons of the UI are critical parts of usability, but at the same time they are the most difficult elements to design. (29.) It is attempting to use them in the design, because they can communicate a whole concept which

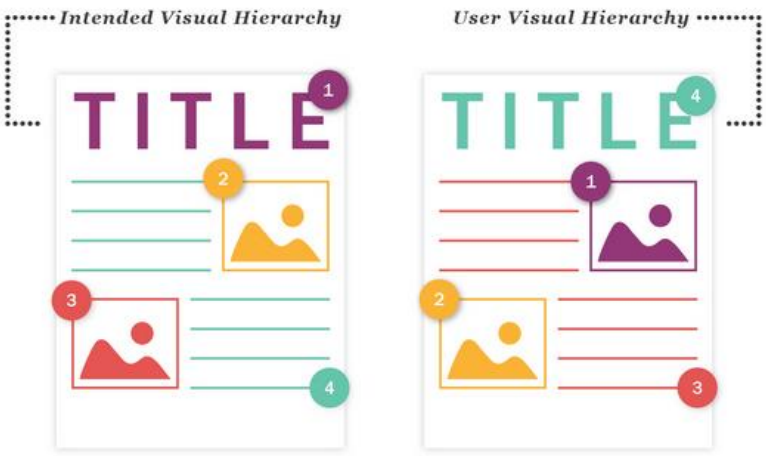

FIGURE 11. Visual hierarchy is the order in which a human recognizes objects on the screen (34.)

would otherwise require several words to explain. In addition, human brain is adept at recognizing symbols (24, p.155.).

Using the icons in applications designed for smart devices saves a lot of valuable screen space. The icons are not depending on the language thus using them in products designed for international markets is beneficial. However, the risk of misinterpretation, which can harm the patient, must be considered. (24, p.155-156.) Comprehension of the icons can be maximized by harmonizing the appearance of them. This includes the following steps:

- Ensuring that several elements represent the same thing by developing a limited set of icons.
- Making icon elements simpler by eliminating confusing details.
- Making similar purpose icons with the same overall size and style.
- Ensuring with usability tests that icons cannot be confused with each other.
- Adding text labels to most critical buttons. (23, p.158.)

The designers of the UI need to pay attention to the physical limitations of a human finger. According to an MIT study, an average human fingertip has a size of 8-10 millimetres. The precision of a finger is naturally limited by that. Major

smart device manufacturers say that the minimum button size must be between seven and nine millimetres. The icon of the button may be smaller, but then it is recommended to leave enough blank space around it. (28.)

Other critical issue is the button placement. Location, position and order are three main things to be considered. This means placing the buttons where users are most likely to find them. (29.)

7.3.3 Colours

Using colours can be a significant improvement in the overall usability of the UI and therefore it is recommended to design it carefully. (24, p.141.) It can have a positive effect on information recognition, discrimination and legibility (24, p.144.). Limiting the colour palette of the UI is recommended, because some harmonious colours repeating themselves give the application a visual balance. There are no regulative restrictions considering the usage of colours, but using them recklessly makes the UI opaque. (23, p.155.) According to human factors researches, the usage of colours can enhance an individual performance in tasks. (24, p.141.)

Researchers have found out that the contrast ratio between objects and background should be at least 7:1 to maximize legibility. Figure 12 demonstrates the importance of an adequate contrast ratio. The best choice for a background colour of white, green and yellow objects is black. On the other hand, black and blue objects are most legible on a white background. (24, p.144-145.)

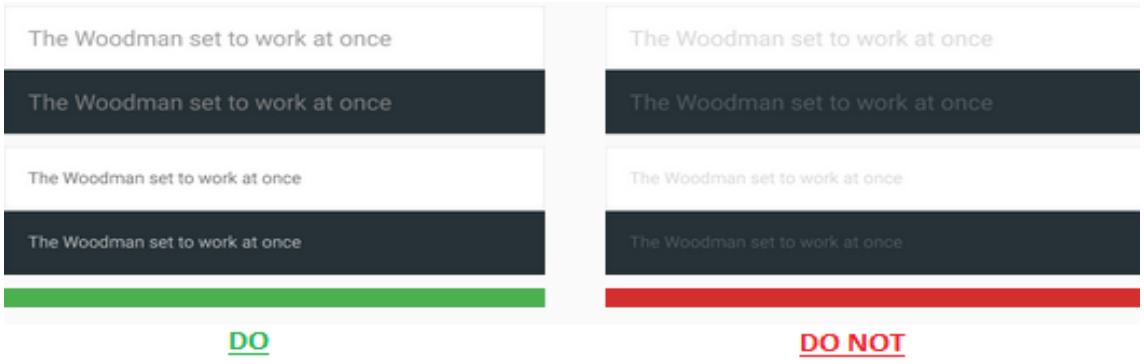

FIGURE 12. Importance of contrast ratio in the UI design (33.)

Ambient lighting of the environment can dramatically affect the human colour perceiving. Low lighting conditions require a strong difference in values between the colour of the object and their backgrounds. The value means the brightness of a colour measured over a range of black to white, but more practically its brightness or darkness. This also helps users with an impaired colour vision. (24, p.145.)

The principles of designing the colour usage in the UI are:

- Using the maximum of five, plus or minus, two colours.
- Using peripheral and foveal colours appropriately.
- Using consistent colour coding.
- Using the same colour for grouping related elements.
- Using colours with a high value and saturation to draw attention. (24, p.146-147.)

7.3.4 Error messages

Informative error messages help the user to understand the device better because the system can describe the problem precisely to the user. The other reason why they are critical for usability is that they occur in situations where the user will not be able to accomplish the desired task. (20, p.142.)

A good error message is phrased in a clear language. It must indicate its meaning without a need to refer to a user manual. Sometimes it is necessary to add system oriented information in the message to help resolve the problem, but the user must be informed to report these codes to the system managers. This kind of information should be placed at the end of a human readable error message to avoid confusion. A precise description is better than a general one. (20, p.142-143.)

Constructive error messages help the user to solve the encountered problem. For example, using the name of the application or functionality that causes the issue in the description. A message can provide options to proceed the execution of the task. If an error is caused by a typing error, a spelling-correction functionality can be the solution. (20, p.143.)

The system must be able to indicate the problem politely to the user. Accusing messages are not practical. A good way to phrase the error is to suggest that it is a fault of the device. (20, p.143.)

The best solution is to prevent the user from getting in this kind of situations. The frequency of the most critical errors can be reduced by asking the user to confirm the intended action. It is important that dialogs are not used too often because the user can get used to automatic answers.

Applications that include different modes are vulnerable for user errors. They cannot always be avoided completely, therefore the current mode must be indicated clearly. Mode can also be indicated with a sound. Using spring-loaded modes means that the user stays in it if button is pressed or some other action is performed. (20, p.145-146.)

7.3.5 Screen density

Blank space between contents helps the user to separate information on the screen. It provides a resting place for the eyes, too. This is important because a medical professional must be able to catch the information they need at a glance. An overstuffed screen can be very intimidating for them. Options for eliminating extraneous information are:

- Using empty space rather than lines to separate content on the screen.
- Stating subjects simply to reduce the amount of text.
- Using simplified graphics.
- Reducing the size of graphics which are associated with brand identity.
- Presenting secondary information on demand through pop-up windows or relocating it to the other screen. (23, p.151-152.)

7.4 Usability tests

The main purpose of medical device usability testing is to understand typical usability issues that users run into. It is a way to evaluate if the medical device is resistant to dangerous use errors that can lead to a deterioration of patient safety (27, p.2.). Usability tests at the summative evaluation phase are carried

out as a part of the validation of the UI. It must be demonstrated that the product can be used safely. As shown in the figure 13, conducting usability tests will take as little as five weeks of working time if arranged effectively.

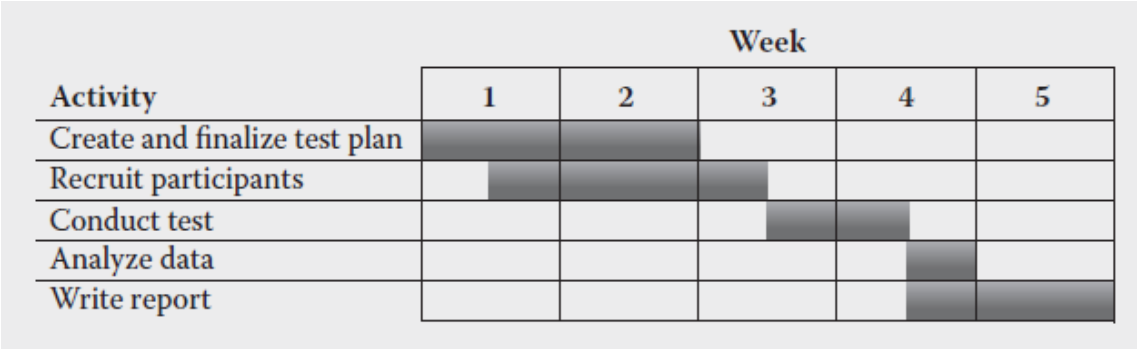

FIGURE 13. Time required for arranging and conducting usability tests. (27, p.41.)

There are many reasons why the manufacturer should invest in usability. Effective usability testing benefits the medical device company by

- informing designers of usability deficiencies before release,
- getting rid of design problems and user frustration and
- improving profitability. (26, p.22.)

Manufacturers of the medical device aim at products that are useful and easy to learn, but at the same time safe and effective. By minimizing design flaws before release, the company demonstrates that goals and priorities of its customers are considered important. This also improves user satisfaction on the product. (26, p.22.) Overall profitability improves because great usability will reduce the amount of service calls and supporting tasks. Happy customers are willing to buy good products in the future. Also, there is a good chance that they will discuss products with their colleagues and increase the sales in that way. (26, p.22.) Table 3 represents the benefits for parties affected by the medical device.

TABLE 3. Benefits of usability testing to different parties. (27, p.10.)

Party	Benefit
Manufacturer	• increases device sales • extends life span of the device • increases customer loyalty • reduces demand of customer support • reduces change of liability claims
Customers	• makes workers more productive • improves worker satisfaction • reduces training and support costs • improves patient care
Caregivers	• improves devices learnability and usability • reduces need for support
Patients	• reduces the risk of serious injury caused by medical device • improves usability

7.4.1 Test plan

The first part of the UI evaluation is to establish a solid plan explaining what, how and by whom will be done during the tests. Planning is the foundation for an evaluation, therefore deciding to go straight into testing without documentation is a mistake that will backfire sooner or later. A good practise is to start writing the plan as soon as possible. Refining of the plan continues as the project proceeds. (26, p.65.) With medical devices, the plan must be ready before tests start. This is because the Usability standard requires the manufacturer to document details of tests and store them in the usability engineering file. Therefore, knowledge of what will be done and documented is required.

The test plan typically includes

- testing purpose, goals and objectives,
- characteristics of participants,
- methods and tools used,
- tasks,
- description of test environment,
- role of the moderator,
- evaluation measures including data to be collected and
- contents of test report. (26, p.67.)

The test plan helps the communication between designers, test moderators and the rest of the team. This is the document that must be reviewed by the development team to ensure that its particular needs are considered in the tests. While everyone is familiar with the plan, it is easier to define required resources. However, the plan must be written with the end user kept in mind. This is because designers easily forget that they are not testing just the product but more its relationship to users with certain characteristics. (26, p.67.)

7.4.2 Recruiting participants

Some people expect that usability tests require a massive amount of test sessions but that is not the case. Studies have demonstrated that even five sessions produce most of the findings of a much larger test event. It has been stated that 5 participants can yield 80% of all possible findings. Using more than 8 participants reduces the results rapidly.

The first usability tests can be conducted with small groups, but while design progresses the amount of the participants usually increases. Summative usability tests involving 15-25 participants with a reasonably homogenous user population are usually enough for medical device regulators. A good practise would be to start first “quick and dirty” tests with a half a dozen participants and double the amount when proceeding to formative tests. Finally, at the summative test phase the number of participants is four times bigger than at the beginning of testing. (27, p.122.)

Thumb rules for test session sample sizes are:

- Six sessions are enough for revealing major problems.
- Twelve sessions provide fairly reliable findings.
- Twenty-five sessions provide reliable findings (27, p.122.)

When recruiting participants for the tests, a good cross-section of users is required. The variables to be controlled include e.g sex, age, education level and work experience. For medical professionals, it would be beneficial to also consider their location (not too much time wasted for travelling), workload, type of institution, special training, experience of operating specific devices and the number of relevant cases per month. Asking for some profession specific questions is a good way to prevent frauds from participating the tests. (27, p.139.)

Maintaining some information of participants in a database is beneficial. In this way the manufacturer can keep a track on participants who are useful for future usability tests, too. Writing a short description of the performance of the participant is recommended after a given test. (27, p.140.)

7.4.3 Testing environment

Traditionally usability tests are conducted in a usability test laboratory. A decent laboratories enable the observation of all interested parties. However, they are expensive and that makes them impractical for some projects. Practically, these tests can be run in many kinds of environments. The actual clinical environment might, however, give a better perspective on contributing factors of the medical device use. (27, p.2.).

Sometimes medical professionals are struggling to find spare time for participating in usability tests. Therefore, conducting usability tests in their workplace might be the only possibility. Testing in an actual use environment is beneficial in some cases because real conditions include situations that cannot be predicted or simulated accurately. (27, p.156.) On the other hand, some complexities must be considered before tests. The testing environment can be cramped, which prevents the participant from performing tasks naturally. Interruptions by real operational needs are possible. This includes both a medical professional

and the space itself. Comprehensive testing requires several hours to be completed, and it is possible that the clinical environment is not available for such a long time. Gaining authorized access to some medical facilities can be difficult. (27, p.157.)

7.4.4 Tasks

Usability tests of medical devices should cover every task that the user is capable of executing. However, a limited duration of the test event might require the manufacturer to prioritize the functionality to be tested. If this is the case, testing must focus on safety-critical parts of the UI. When proceeding from a formative to a summative evaluation, this becomes even more crucial. As regulator's job is to protect the public from dangerous medical devices, their recommendation is that both types of testing focus on tasks that are most critical. At the summative evaluation phase tasks need to be linked to risk management and analysis efforts. Developing a prioritized user task list utilizing the risk management information is a straightforward job to do. However, it is the most critical part of the usability test planning. Factors affecting the task selection are:

- Type of test.
- Complexity of design.
- Design progress.
- Prototype capabilities.
- Design decision making. (27, p.204-206.)

7.4.5 Examples for usability testing methods

Information provided on the medical devices screen must have good legibility. Legibility means people's ability to discern details on the screen. It is sometimes confused with readability, which refers to an ability to acquire information from a display. (27, p.231.) The contents provided in the form that designers approve may not be legible to users. That is because many things, for example visual impairments, compromise the legibility of view. Figure 14 demonstrates the effects of different visual impairments on the human vision.

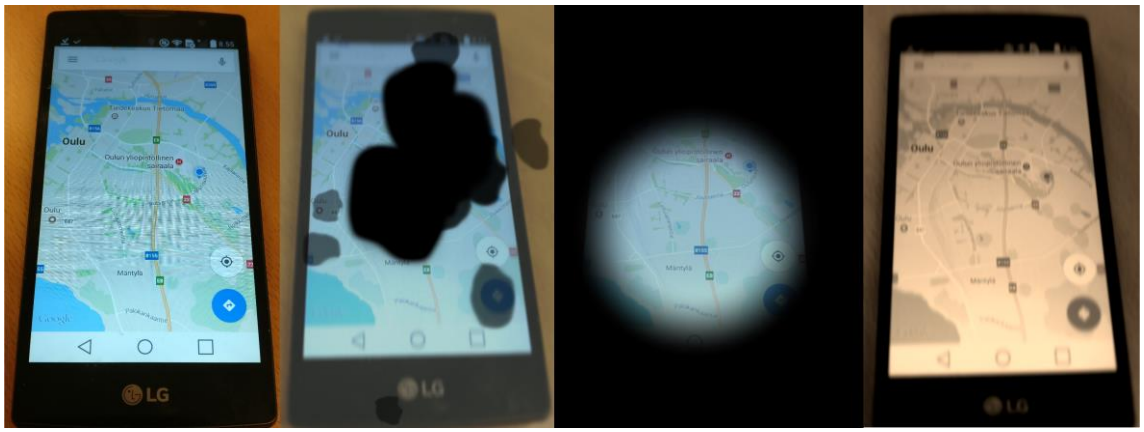

FIGURE 14. Normal vision compared to the vision of a human suffering from diabetic retinopathy, claucoma and cataract.

It can be tested by observing if participants commit reading errors or comment that something on the screen is unreadable. In addition to these passive methods, the participant can also be asked to read the contents of the screen from a predefined distance thus estimating their reading accuracy. The tester must ensure that all participants are viewing the design from the precisely same distance. (27, p.229.) Testing approaches may include asking ratings of legibility of the information and suggesting participants to read the contents of the screen at a maximum viewing distance. (27, p.231.)

Symbols are important especially with UIs that are operated by mobile devices because valuable space of the screen can be saved by using them. They are also beneficial if the product is going to be sold on international markets (27, p.228.). A characteristic of a good symbol is an ability to communicate its meaning quickly and undoubtedly. (27, p.226.)

A comprehension test is a good practice for testing the usability of the symbol. This means that the test participant is given only a little piece of context where the symbol is appearing. Then, symbols are presented in isolation one at the time and the participant is asked to interpret their meaning. It is recommended to require a brief definition of symbols. If the participant cannot provide it, they can be asked to take their best guess. (27, p.227.) The test can be adjusted to be more demanding by showing the icon just a few moments before hiding it.

Other good ways to conclude their usefulness is asking the participant to link a symbol and its written meaning together or creating a multiple-choice test. (27, p.226.) Testing of symbols must demonstrate that they cannot be confused in a manner that leads to patient injury (27, p.228.).

Alarm systems are very critical for the efficiency and safety of a medical device. All alarms may not require the operator's immediate response but they are still important. An efficient alarm includes both visual and audible components. It must be able to

- draw the user's attention,
- indicate the level of criticality of the situation,
- tell the user what is wrong and
- suggest the correct action to resolve the alarm condition. (27, p.218.)

An alarm system can be tested by observing if it efficiently serves these purposes. A good way to evaluate it is to trigger an alarm while the participant performs routine tasks with the device. This reveals alarms which work as intended, but also the ones which do not. (27, p.219.)

7.4.6 Documentation

Usability tests give designers an overall sense of the strengths and weaknesses of the UI. Data to be collected describes participant's behaviors and opinions related to the evaluated design. Documentation typically includes data demonstrated in table 4. The pertinence of test data depends on the type of the test to be conducted. If tests are run to compare the effectivity of two similar products, then task times are extremely relevant. (27, p.300.)

The most valuable data that usability tests can produce are task completion and use error rates. Task times are also feasible but they do not tell much about the overall UI quality. If it enables the user to move from one task to another too swiftly, it can lead to use errors and patient harm. Task times can also be distorted by e.g thinking aloud. One way to increase the relevancy of task times is simply to ask the participant to work silently. Observing the consistency of task

times within participants is a better option than looking for an individual performance. (27, p.305.)

Unusual data points occurring in the usability tests are called outliers. The term is also used by some usability specialists to describe unqualified participants. Briefly stated, outlier differs from other data points significantly and therefore suggests that a measuring error exists. A simple strategy to get rid of outliers is to reject values that differ too much from the mean value of the data set. Usability specialists, however, recommend characterizing the participant as an outlier rather than a single data point. (27, p.317.)

TABLE 4. Examples of data gathered during usability tests.

Data	Description
Task times	• how long does it take for the participant to complete the given task
Completion rate	• with or without the need for operator's guidance • correctly or incorrectly • inside time limits or not
Use error rates	• this is based on a predefined list of potential use errors
Judgements of selected attributes	• ease of use • perceived task speed • visual appeal
Pertinent verbal comments	• write down relevant observations of device use and user behavior

8 CONCLUSION

European regulations concerning medical devices are quite versatile. The medical device directive gives requirements for essential performance and safety. Every single part of the medical device need to be assessed with the risk control in mind. Although stated otherwise in the directive, complying with the requirements of harmonized standards is the only practical way to demonstrate conformity with the directive and to gain access to the markets of medical devices.

The main goal of this thesis was to figure out the regulative requirements for medical application design and implementation in the European market area. The second objective was to gather requirements and relevant information concerning the usability tests. The third objective was to compare the gathered information to the existing implementation of the application.

The regulative section of this thesis describes clearly the aspects that need to be considered on the design. A quite large package of information concerning usability tests has also been presented. The application design and implementation tasks have been ongoing in the background, but they were left out of this thesis due to their confidential nature.

Medical device design is a technical process where clinical needs and environmental considerations must be thoroughly researched and understood. Usability engineering must be a part of product design from the scratch all the way through to the summative testing of the medical device.

The contents of this thesis work provide means to design an application which satisfies both regulators and customers. The subjects discussed in this work gave the author a new perspective of the importance of usability and testing of it.

REFERENCES

1. Medical devices - Regulatory framework. European commission. Date of retrieval: 17.7.2017. http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_fi.
2. Terveydenhuollon lakisääteiset vaatimukset kansainvälisillä markkinoilla – Suomi ja EU fokuksessa. Ståhlberg, Tom 2015. Date of retrieval: 17.7.2017. https://www.tekes.fi/globalassets/julkaisut/terveydenhuollon_laitteiden_lakisaateiset_maaraykset_opas.pdf.
3. Pöyhönen, Ilpo – Kylmälä, Kaarle 2010. EU:n lääkintälaitedirektiivin mukaisten terveydenhuollon tuotteiden suunnittelu ja valmistus viranomaisvaatimukset huomioiden. Helsinki:Terveysteknologian Liitto ry, FiHTA.
4. Purojärvi, Joni 2010. Medical device software development with enhanced Scrum. Jyväskylä: University of Jyväskylä, Information technology. A thesis.
5. ISO 14971:2007. 2007. Medical devices – Application of risk management to medical devices. Geneva: International Organization for Standardization.
6. ISO 13485:2016. 2016. Medical devices – Quality management systems – Requirements for regulatory purposes. Geneva: International Organization for Standardization.
7. IEC 62304:2006. 2015. Medical device software – Software lifecycle processes. Geneva: International Organization for Standardization.
8. ISO 62366-1:2015. 2015. Medical devices - Part 1: Application of usability engineering to medical devices. Helsinki: Finnish Standards Association.
9. Standard IEC 62304 – Medical Device Software – Software Lifecycle Processes. Jordan, Peter 2006. Date of retrieval: 3.8.2017. http://ieeexplore.ieee.org.ezp.oamk.fi:2048/document/4126152/.
10. ISO 60601-1. 2007. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. Helsinki: Finnish Standards Association.

11. Quality Management System & ISO 13485. Date of retrieval: 7.8.2017. http://www.johner-institute.com/articles/qm-system-iso-13485/.
12. How to develop a smartphone App to be FDA-cleared or CE Marked? – part 2 IEC 62304 and agile methods. Michaud, Cyrille 2013. Date of retrieval 8.8.2017. http://blog.cm-dm.com/post/2013/12/03/How-to-develop-a-smartphone-App-to-be-FDA-cleared-or-CE-Marked-part-2-IEC-62304-and-agile-methods.
13. Riskitietoisen ohjelmiston vaatimusmäärittelyprosessin kehittäminen. Pöyhönen, Ilpo – Hukki, Kristiina 2004. Date of retrieval: 8.8.2017. http://www.vtt.fi/inf/pdf/tiedotteet/2004/T2263.pdf.
14. Lääkintälaitteiden ohjelmistot – Suunnittelun kehityskohteita vesiputous- ja XP-mallin näkökulmasta. Pöyhönen, Ilpo 2005. Date of retrieval: 8.8.2017. http://www.vtt.fi/inf/pdf/tiedotteet/2005/T2320.pdf.
15. Software process improvement to assist medical device software development organisations to comply with the amendments to the medical device directive. McHugh, M – McCaffery, F – Casey, V 2012. Date of retrieval: 8.8.2017. http://ieeexplore.ieee.org.ezp.oamk.fi:2048/document/6334808/.
16. Developing Medical Device Software to IEC 62304. Hall, Ken 2010. Date of retrieval: 11.8.2017. http://www.mddionline.com/article/developing-medical-device-software-iec-62304.
17. Usability for Medical Devices: A New International Standard. Hodgson, Philip 2010. Date of retrieval: 14.8.2017. http://www.userfocus.co.uk/articles/ISO62366.html.
18. Ohjelmiston markkinoille saattaminen lääkinnällisenä laitteena. Toivonen, Tuomas 2015. Date of retrieval: 18.8.2017. https://www.stedi.fi/data/documents/Ohjelmisto-MDD-Stedi-5-5-2015.pdf.
19. Usability testing: Validating UI design. 2007. Date of retrieval: 18.8.2017. http://www.mddionline.com/article/usability-testing-validating-user-interface-design.
20. Nielsen, Jakob 1993. Usability Engineering. San Diego: Academic press.

21. IEC 60601-1-11. 2015. Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Geneva: International Electrotechnical Commission.
22. SFS-EN 60601-1-8:2006. 2007. Medical electrical equipment – Part 1-8: General requirements for basic and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. Helsinki: Finnish Standards Association.
23. Wiklund, Michael – Wilcox, Stephen 2004. Designing usability into medical products. Florida: CRC Press.
24. Wiklund, Michael 1995. Medical Device and Equipment Design – Usability Engineering and Ergonomics. Buffalo: Interpharm Press.
25. Export statistics. Healthtech Finland 2017. Date of retrieval: 25.8.2017. http://healthtech.teknologiateollisuus.fi/en/info-about-industry/export-statistics.
26. Rubin, Jeff – Chisnell, Dana 2008. Handbook of Usability Testing, Second Edition: How to Plan, Design, and Conduct Effective Tests. Indianapolis: Wiley Publishing Inc.
27. Wiklund, Michael – Kendler, Jonathan – Strochlic, Allison 2011. Usability testing of medical devices. Boca Raton: CRC Press.
28. User Interface Design for Touch Screen Displays 2016. Date of retrieval: 1.9.2017. http://newvisiondisplay.com/ui-design-touch-screen-displays/.
29. 7 rules for mobile UI button design. Date of retrieval: 1.9.2017. https://uxplanet.org/7-rules-for-mobile-ui-button-design-e9cf2ea54556.
30. Sutherland, Ashley – Cavanagh, Matt 2016. Coming Home: Designing For Medical Device Use Environments. Date of retrieval: 6.9.2017. https://www.meddeviceonline.com/doc/coming-home-designing-for-medical-device-use-environments-0001.
31. The EU Medical Devices Regulation (MDR 2017/745). Date of retrieval: 7.9.2017. http://www.intertek.com/auditing/medical/mdr-2017-745/.

32. Patterns – Navigation drawer. Google 2016. Date of retrieval: 8.9.2017. https://material.io/guidelines/patterns/navigation-drawer.html#navigation-drawer-behavior.
33. Usability – Accessibility. Google 2016. Date of retrieval: 8.9.2017. https://material.io/guidelines/usability/accessibility.html#accessibility-principles.
34. The Value Of Eye-Tracking software In Medical Device Usability Testing. Rahman, Mahajabin 2016. Date of retrieval: 8.9.2017. https://www.meddeviceonline.com/doc/the-value-of-eye-tracking-software-in-medical-device-usability-testing-0001?platform=hootsuite.