System Concept Development for an Asthma & COPD Telehealth System

Version 1
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1. INTRODUCTION

1.1. Purposes of the system to be developed

COPD is among the 10 most prevalent chronic conditions, and occupies a substantial proportion of the available health-care resources. It is similar in its symptoms to asthma - coughing, wheezing and difficulty breathing - and they share similar diagnosis and treatment methods (Shaya et al. 2008). The major difference between the 2 conditions is their prognosis: unlike asthma, COPD gets progressively worse over time, with treatments aiming to slow the decline rather than stop it. (Bellamy, 2005)

This system is intended for those patients who have been diagnosed with COPD, or who are at high risk of COPD (smokers in particular-according to Bellamy (2005)), as well as their GPs, and any surgeon or consultant physician who needs access to their data.

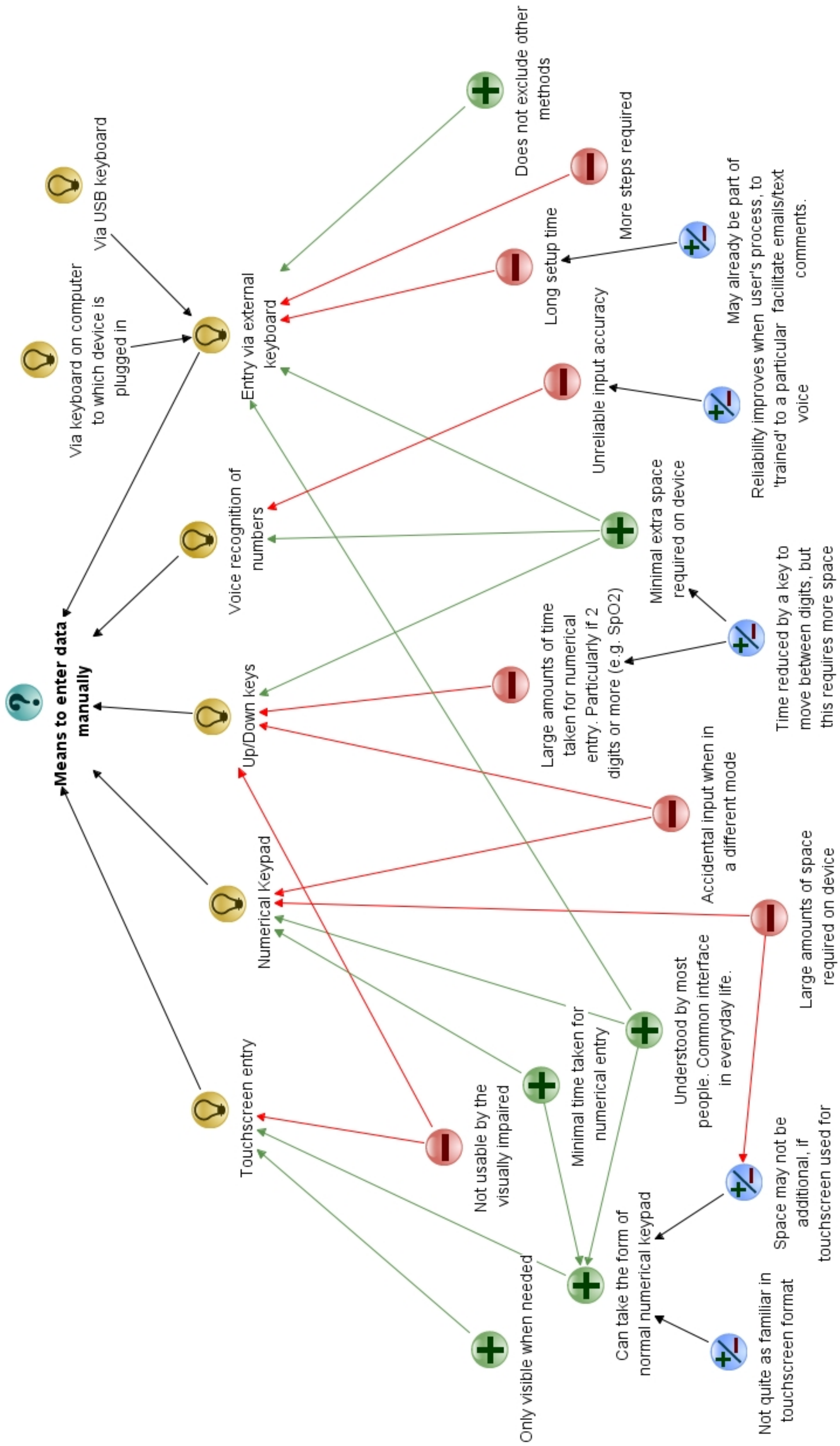
- The aim of this telehealth system is to monitor COPD condition over time with medical professional
- It shall be suitable for deaf or blind people
- It shall measure correlates of COPD (FEV, FVC, PEV) with minimal error
- It shall transmit the information to the patient’s GP
- It shall convey comments between GP and patient

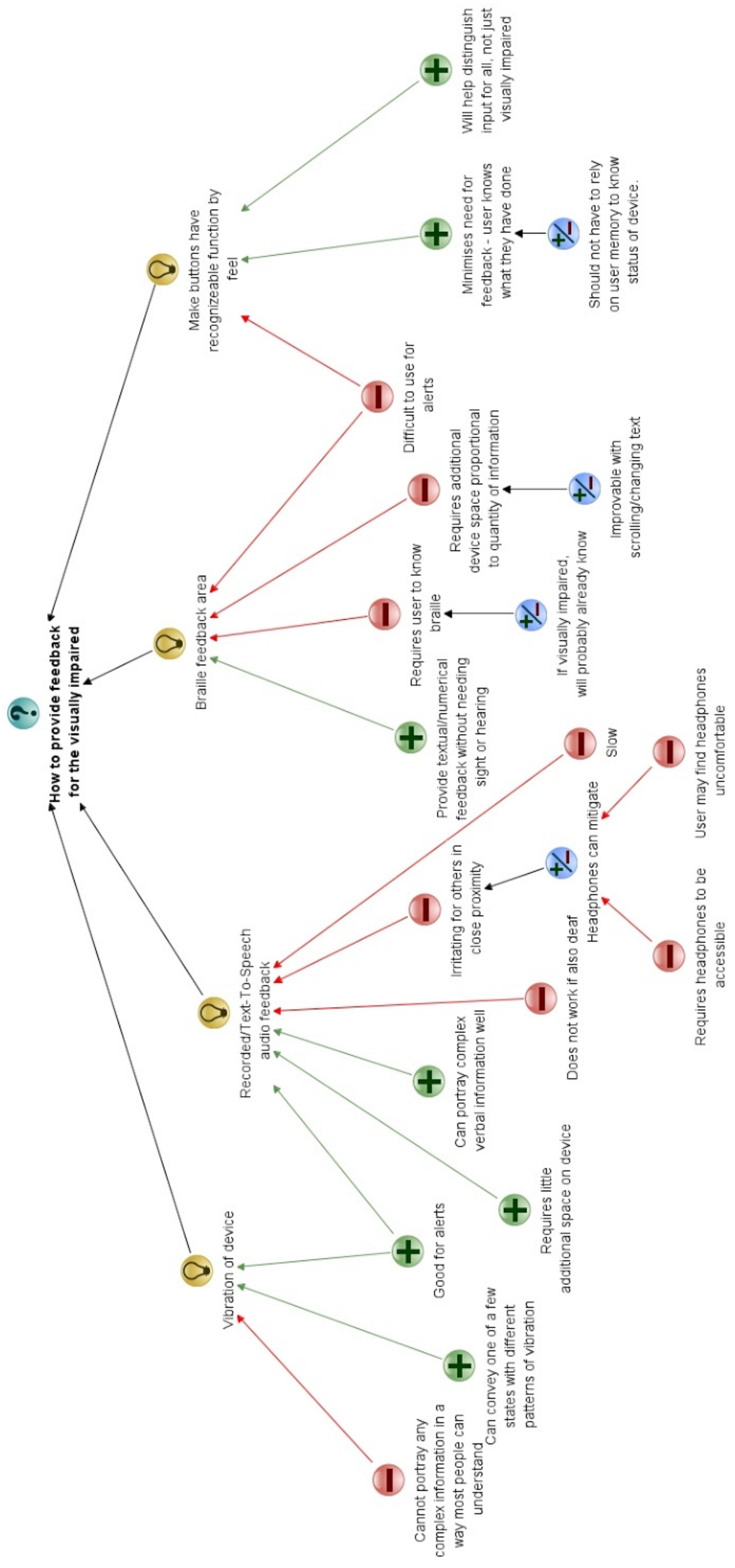
1.2. Main system functions to be implemented

- FEV/FVC/PEV measurement via mouthpiece
- Error detection for user measurement technique
- User override of false positive errors
- Ability to undo errors
- Permanently accessible help button
- Manual numerical data input
- Inputting and sending audio and textual comments
- Sending information wirelessly
- Displaying complex feedback for sighted and non-sighted individuals
- Battery charging

2. DESIGN RATIONALE

2.1. Issue Maps




How to provide feedback for the visually impaired
Make buttons have recognizeable function by feel
Will help distinguish input for all, not just visually impaired
Minimises need for feedback - user knows what they have done
Should not have to rely on user memory to know status of device.
Difficult to use for alerts
Braille feedback area
Requires additional device space proportional to quantity of information
Improvable with scrolling/changing text
Requires user to know braille
If visually impaired, will probably already know
Provide textual/numerical feedback without needing sight or hearing
Recorded/Text-To-Speech audio feedback
Slow
User may find headphones uncomfortable
Headphones can mitigate
Irritating for others in close proximity
Requires headphones to be accessible
Does not work if also deaf
Can portray complex verbal information well
Requires little additional space on device
Vibration of device
Good for alerts
Can convey one of a few states with different patterns of vibration
Cannot portray any complex information in a way most people can understand

2.2. TRIZ Application

2.2.1. Manual data input - Physical contradiction

One problem that has arisen based on the issues raised in Issue Map 1, is that the user needs to be able to input data manually, however the area on the device is limited. The method that is the most reliable, fast and understood would be a numerical keypad on the device itself, however buttons on the device would take up a lot of space, and may be pressed accidentally at the wrong time. This is made more challenging by the fact that the dexterity of users, given their age, is likely to be low (Carmeli, Patish and Coleman, 2003). Buttons will also likely be required for more functions, necessitating even more of them.

This can be expressed using the TRIZ model of physical/inherent contradiction:

- ➔ There should be more buttons
- ➔ There should be fewer buttons

Bearing in mind Rantanen and Domb's (2008:53-55) suggestion to intensify contradictions:

Considering a **separation in space**:

- The buttons could be moved to a place on the device
- The buttons could be moved to a fold/flip/slide-out section
- The buttons could be moved to a separate device
    - The device could plug into the primary device so that they are carried together
    - The device could be a wired/wireless input device
    - Use the buttons from a PC (require device plugged in)

Considering a **separation in time**:

- The buttons could be unavailable except when needed
    - They could be covered by a slide/flap cover
    - They could be flush with the case until needed, then raise up

Considering a **separation in condition**:

- The buttons could perform different functions at different times, lit to show which function they currently are used for

Considering **separation in super/sub-system**:

- If it is known that the manual entry is limited to a specific number of digits, the numbers could make a wheel for each digit (similar to a combination lock) - each wheel subsystem has the full set of button numbers, but the supersystem has only few wheels
- A single wheel (limitless, slower input) or dial (limited, faster input) could input numbers
- The buttons could be made to latch (possibly as switches) to act as binary digits - fewer buttons in the subsystem (the physical buttons) could allow more button permutations in the conceptual supersystem (e.g. $2^7 = 128$, so if numbers needed are known to be below this, such as for SpO_2 (0-100%), then only 7 buttons/switches are needed).

Chosen solution: 3 digits of wheels with braille bumps and high contrast written number

2.2.2. Tactile feedback for the visually impaired - Technical contradiction

Braille feedback would allow the device to convey complex verbal/numerical information to visually impaired users, however the more information is needed, more real estate must be used to display it. Given that the maximum desired message length is unknown (GP may want to comment on a number of things) a variable length message must be accounted for. As a result, the braille area must be able to scroll, or change to the next section of text somehow. Some people read braille at speeds up to 400wpm (Ford and Walhof, 2007). The device must display enough (variable-length) information, at an appropriate speed, in a small fixed area.

This can be framed as a TRIZ technical contradiction in multiple ways:
The text could be considered immobile or mobile, considering its location is physically static, but its information is certainly changing, and possibly moving. The more info shown the better.

Improving feature	Worsening feature	Suggested principles
24 - Loss of information	4 - Length of immobile object	26
24 - Loss of information	3 - Length of moving object	1, 26
24 - Loss of information	26 - Amount of substance	24, 28, 35

Thus the principles suggested to consider are:
1 - Segmentation
- The line of text could be broken into multiple lines
- The line of text could be displayed one segment at a time

24 - Mediator
- A braille reader could be attached to the device

26 - Copying
- The message could be copied from digital form onto inexpensive ticker tape (common method for this is pricking holes in paper, leaving raised bumps)

28 - Replacement of mechanical system
- Use capacitive ‘field’ from finger to determine how much of the text has been read, in order to decide when to switch/scroll to the next segment

35 - Transformation of properties
- Change character density/scale to fit on more/fewer characters as needed

Chosen solution: Multi-line text, with previous lines replaced by next segments as capacitance of finger moves over subsequent lines. At least half of the next line has to be read before the previous line changes to minimise false positives. When the message finishes, it wraps around to the beginning again, as with scrolling text on LED matrices.

A remaining issue is the placement of the braille display - it still needs to take up some room.

2.2.3. Placing a braille display - Ideal final result and resources

The ideal final result is expressed in TRIZ as:

$$IFR = \frac{Benefits}{Costs + Downsides}$$

As such, an ideal solution to a problem with a system is has no downsides, and requires no costs additional to what is already in the system, leaving only benefits. This will be aimed for in finding a location for the braille display.

One way to achieve this is looking at the available resources in the system using 9 windows:

	Past	**Present**	**Future**
Supersystem	User blowing into device, user receiving alert of message from GP, GP sending message	User holding device	User sending data and/or comments to GP, user putting device away, reading other data with a braille reader
System	Device measuring airflow	Telehealth device	Device encrypting and sending data, in charging station
Subsystem	Motors for vibration, speakers for audio alert, integrated spirometry digitiser	Screen area, existing buttons/input, mouthpiece, device body	Internet connection chip/IC

1) Present subsystem - The braille could be positioned on the back of the device body, however this would require the user to hold the device awkwardly to interleave reading the feedback with inputting data and taking measurements.

2) Present subsystem - The real estate taken up by the screen is not needed if the user cannot see, so the area could instead be replaced with braille feedback for those who need it, either as a separate whole device, or an interchangeable separate module.

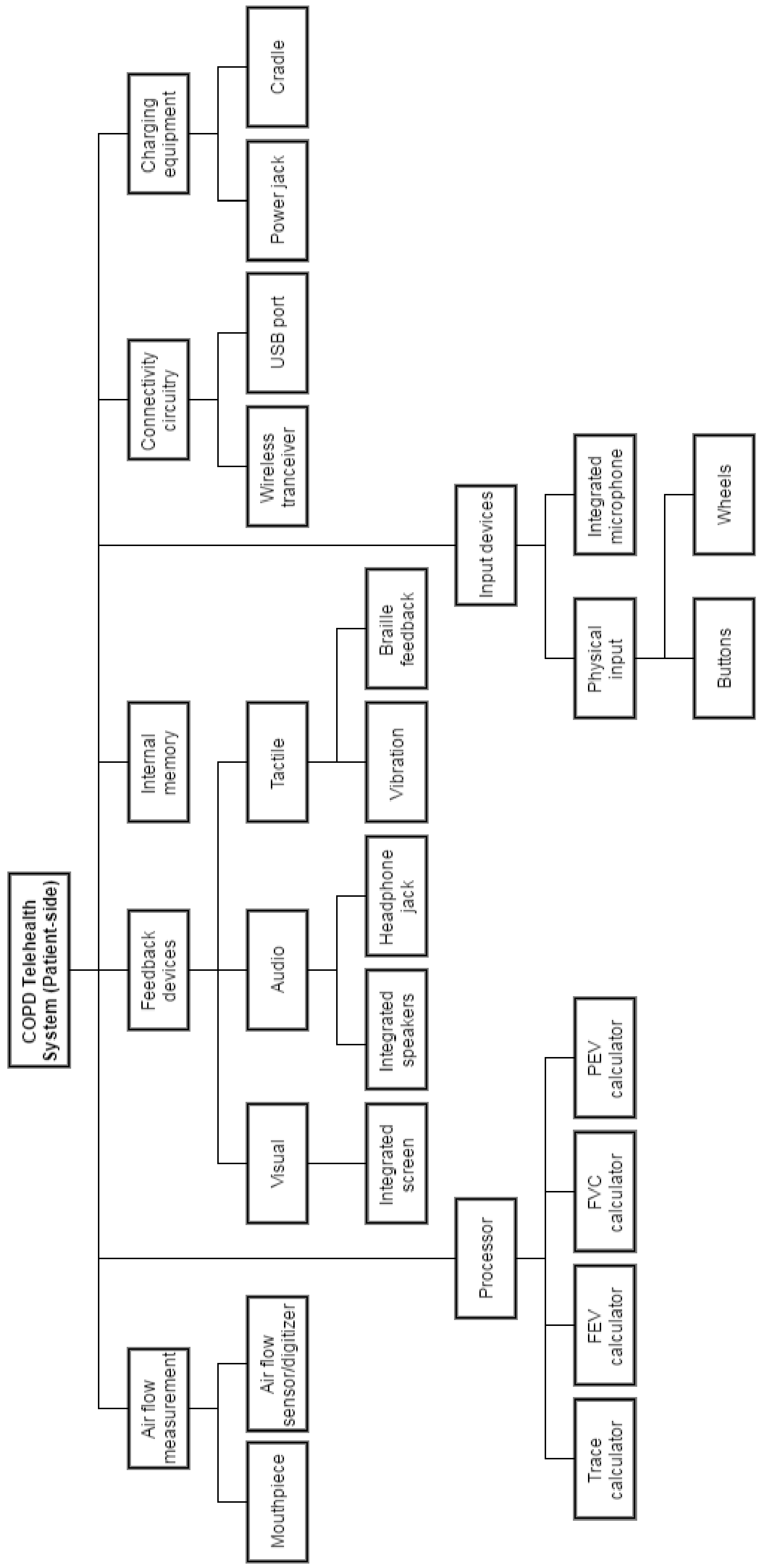
3) Future supersystem - Plug in braille reader, obviating the need for feedback on device.

4) Present subsystem - Put braille feedback on top of screen - display bumps using Principle 29 - pneumatics/hydraulics - have a matrix of capsules that can be filled to create bumps in the characters needed and use the capacitance of a touch screen to locate finger position.

Chosen solution: (4) (with the option of 3) - takes advantage of existing capacitance of touch screen, and positions the display in an accessible place for one or two hands.

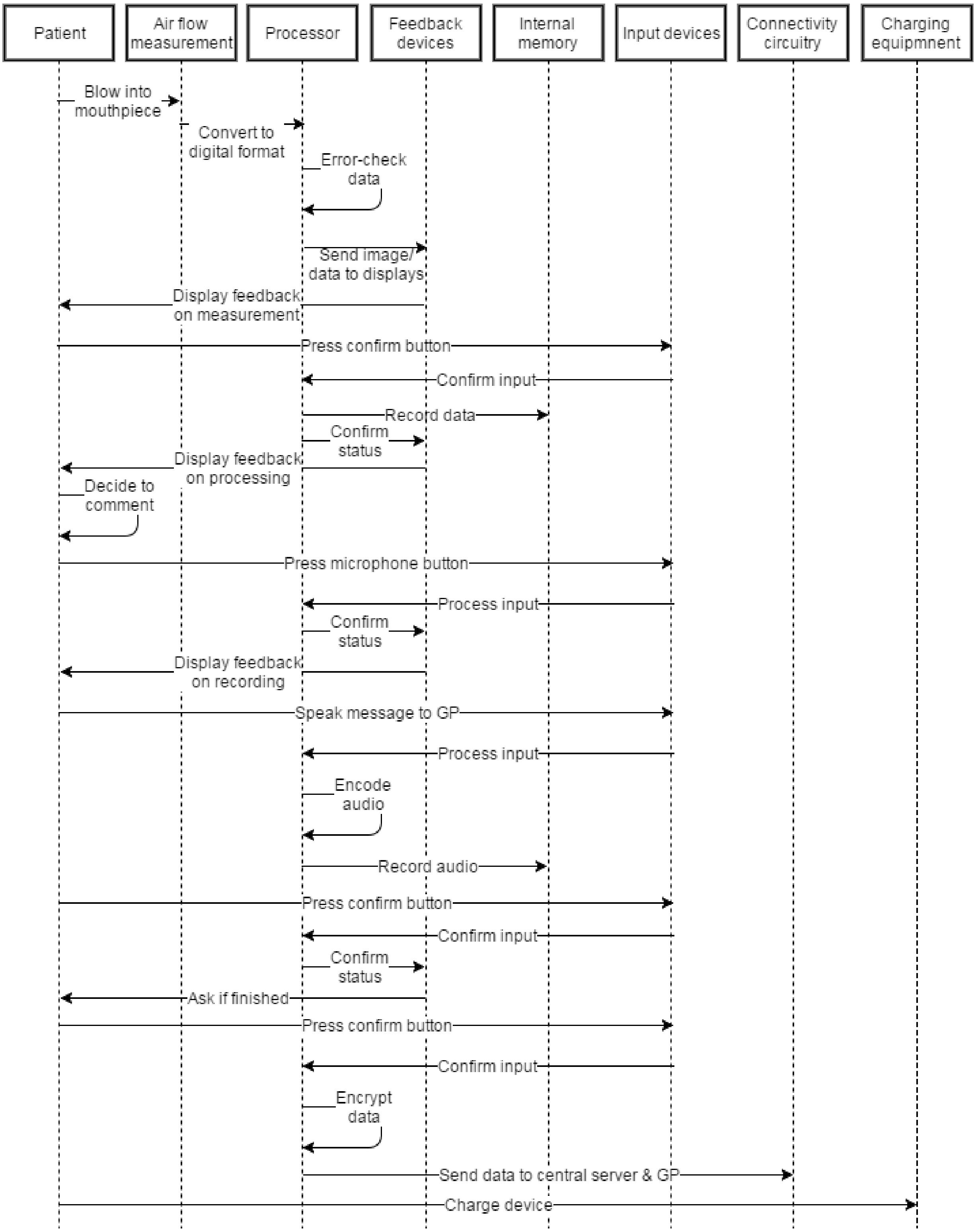
3. CONCEPT SOLUTIONS

3.1. System Structure - Block Definition Diagram:

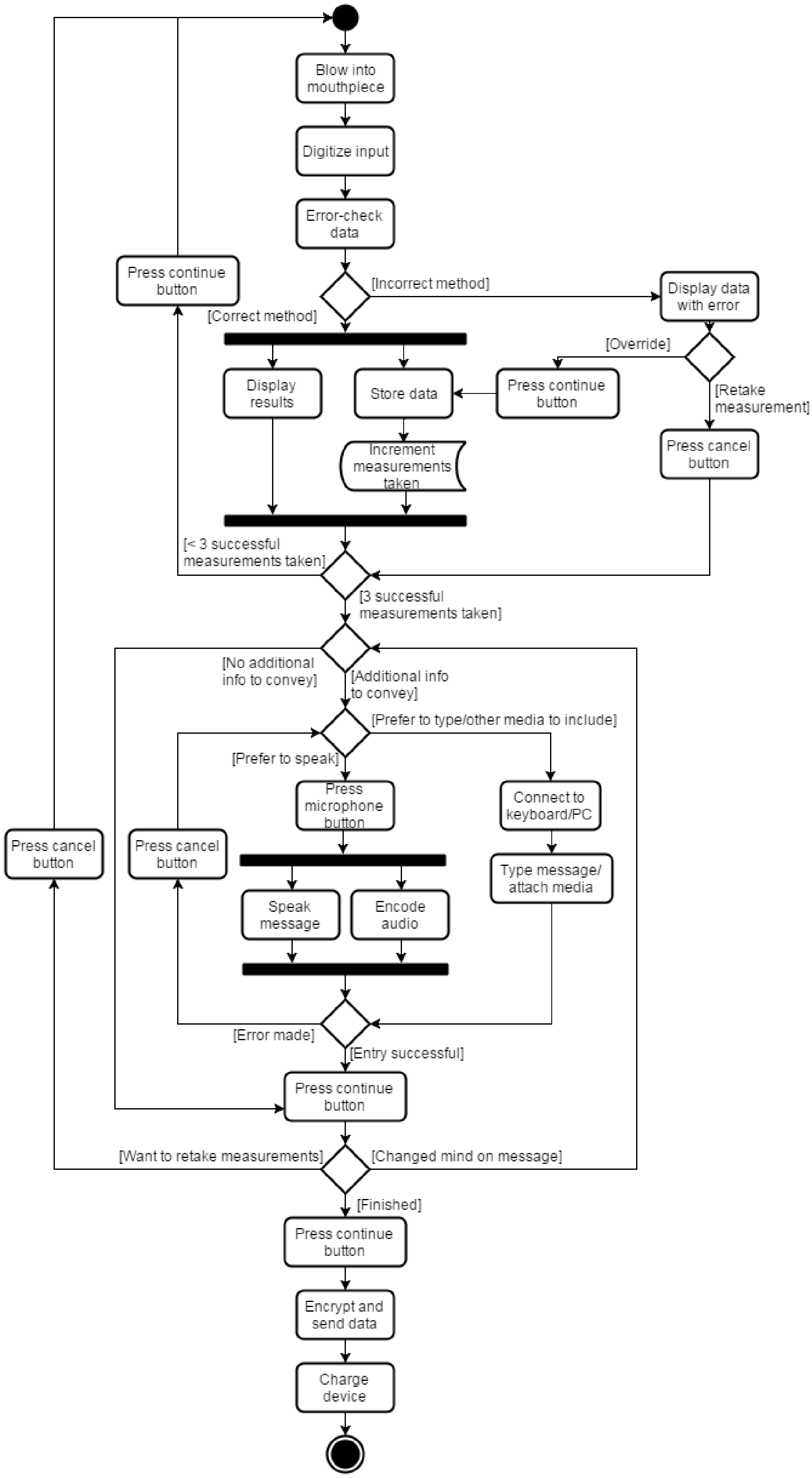


3.2. System Behaviour

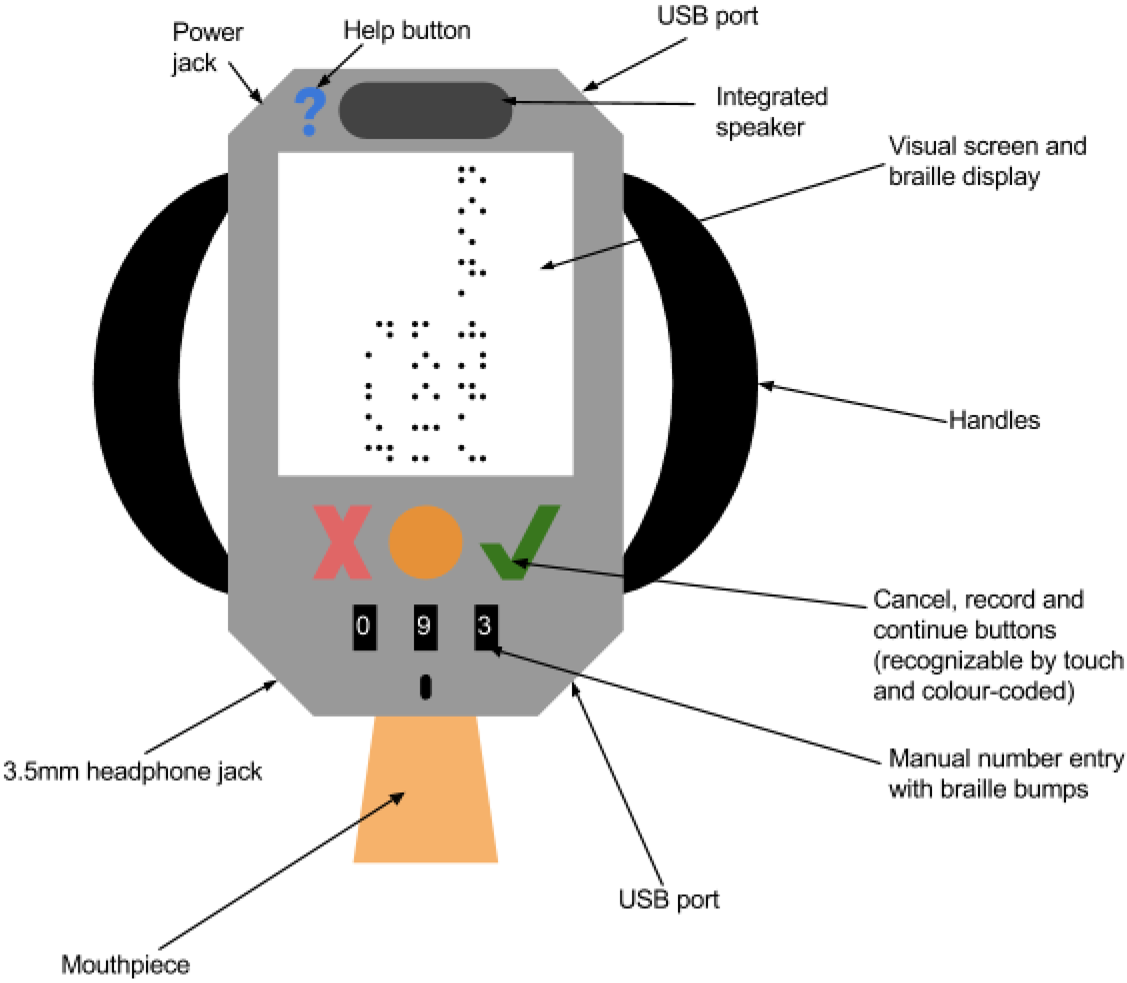
3.2.1. Sequence diagram



3.2.2. Activity diagram



3.3. System Layout



3.4. System Interfaces

3.4.1. Input

- 3-buttons control typical use.
- Always-available help button
- Wheels for manual data entry
- Record audio with integrated microphone or plug in USB keyboard

3.4.2. Feedback

- Primary information given on screen visually and/or in braille
- Audio feedback through speakers or headphones
- Plug braille reader or other feedback module into USB port

4. RISK ASSESSMENT

4.1. Failure Mode and Effects Analysis (FMEA) table

FMEA can be used for the full spectrum of risk analysis: BS EN 31010:2010 describes it as ‘strongly applicable’ for risk identification; risk analysis of consequence, probability and level of risk; and risk evaluation (British Standards Institute, 2010).

#	Function	Potential failure mode(s)	Potential effect(s) of failure	SEV	Potential cause(s) of failure	PROB	Current design control	Risk Score	Recommended Action(s)	New Risk Score
1	Blow into mouthpiece	As well as	Choke	4	Debris inside back to mouth	2	None	**8**	Provide mouthpiece cover	**4**
2	Blow into mouthpiece	As well as	Illness	3	Mouthpiece holds bacteria/ viruses	3	Cleanable/ disposable mouthpiece	**9**	Antibacterial coating	**3**
3	Digitize input	None	Reputati-on damage	3	Faulty components	3	High quality components	**9**	QA test each device	**6**
4	Error-check data	Too little	COPD progress unknown	4	Bug in software	3	Error heuristics	**12**	Fully test algorithms with users	**8**
5	Speak message to GP	Too much	Private data leak	3	Finish button not fully pressed	3	None	**9**	Vibrate/ audible & tactile click on button press	**6**
6	Encrypt data	None	Private data leak	4	Bug in software	2	Coder skill	**8**	Test-driven development of key code	**4**
7	Charge device	Too much	Electroc-ution	5	Power surge	2	Grid trip switches	**10**	Integrate surge protector in charger	**5**

SEV: Severity, (1-5), PROB: Probability (1-5)
Risk Score = (Severity) x (Probability)

4.2. Risk matrix (before recommended actions)

Severity	5		7			
	4		1,6	4		
	3			2,3,5		
	2					
	1					
		1	2	3	4	5

Probability

4.3. Risk matrix (after recommended actions)

Severity	5	7				
	4	1,6	4			
	3	2	3,5			
	2					
	1					
		1	2	3	4	5

Probability

References

Bellamy, D. 2005. *Spirometry in Practice: A Practical Guide to Using Spirometry in Primary Care*. 2nd ed. [ebook] London: BTS COPD Consortium. Available at: https://www.brit-thoracic.org.uk/document-library/delivery-of-respiratory-care/spirometry/spirometry-in-practice/ [Accessed 15/03/2016].

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