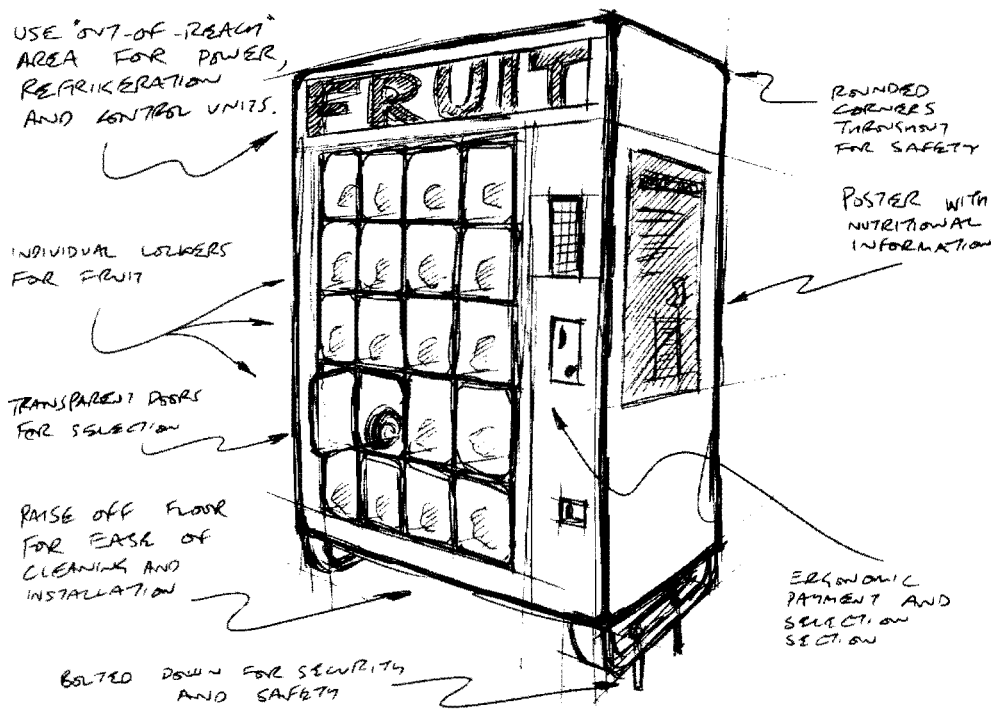


1(a) Many approaches are possible, but potential solutions should reflect consideration of:

- the means of storing the fruit (individual items or all together, loose or protected),
 - whether 'the user goes to the fruit' or 'the fruit goes to the user',
 - if the fruit drops, how its accelerations might be controlled.
- [30%]

(b) Embodying the solution in a vending machine design should reflect the issues that would be considered in a requirements specification, including: materials, safety, ergonomics, appearance, operation, maintenance and costs. Consideration of other lifecycle stages would be advantageous, including: production, distribution, installation, assembly and recycling. For example:



(c) Various answers are possible. For example,

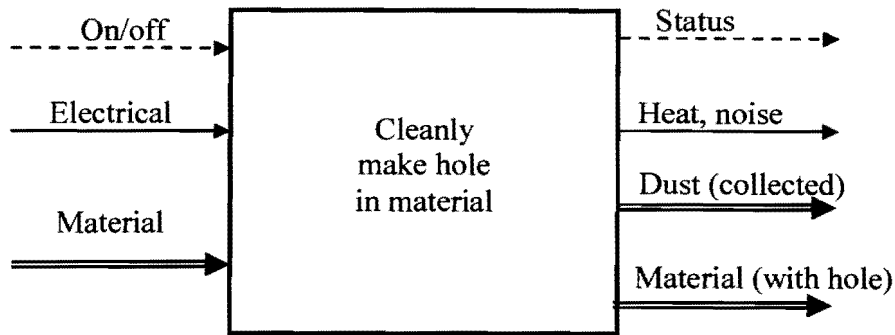
- 0: "a product that dispenses fresh fruit in return for coins, that is the same size and shape as standard refrigerators (approximately $2m^3$), and that contains an electrically powered refrigerator."
 - 1: "a product that dispenses fresh fruit in return for students' coins" (the product's size and the means of keeping fruit fresh have now been left undefined).
 - 2: "a product that dispenses healthy snacks in return for students' payment" (means of payment has now been left undefined).
 - 3: "a product that dispenses healthy snacks upon demand" (snack type has now been left undefined).
- [10%]

- (d) Various answers are possible. For example,
- 4: “a system of delivering healthy snacks” (the requirement for a vending machine has now been omitted).
 - 5: “a system that encourages healthy eating” (the requirement for the provision of snacks has now been omitted).
 6. “a system to improve people’s diets” (the requirement to use encouragement has now been omitted – enforcement is possible). [10%]
- (e) A useful tactic here is to identify the various top-level categories into which different approaches might fall to ensure broad coverage:
- *Promotion*: use media channels to promote healthy eating.
 - *Legislation*: legislate against the sale of unhealthy foodstuffs to minors.
 - *Financial*: make healthy foods economically attractive (through taxation or otherwise).
 - *Institutional*: change food provision for school meals and snacks.
 - *Familial*: educate parents about child nutrition. [20%]

Examiner's comment:

This was a popular question. (a) Most candidates developed three alternative design solutions that were significantly different to each other, but some failed to comment on the strength and weaknesses of each one. (b) Only a few candidates developed their solutions to part (a) to any great degree, and fewer still truly considered how their chosen design would meet all the requirements of the brief. (c) and (d) Almost all candidates were able to abstract the problem statement up to and beyond what the company could reasonably address. (e) Relatively few candidates considered the broad range of approaches that a government could adopt. Using the creativity methods discussed in the lectures would have helped with this.

2 (a) An overall function for the device might be represented as follows (with energy, signals and materials considered):

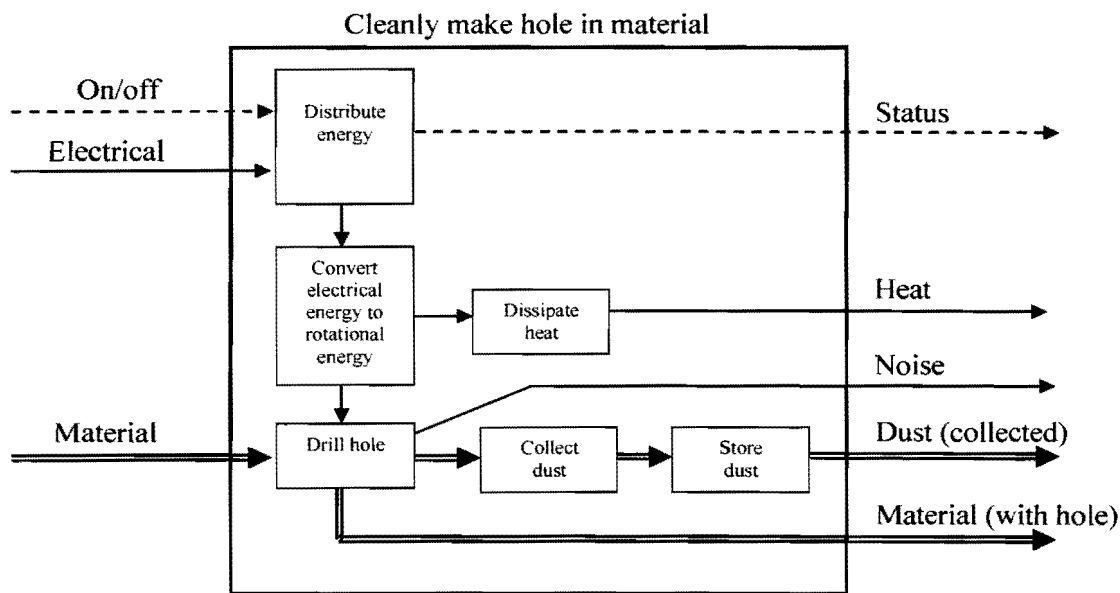


[10%]

(b) A product's sub-functions are the various functions (or roles or tasks) that collectively contribute to the performance of the product's overall function. A product's components are the various modules (or bits or parts) that the product is (e.g. physically) made up of. The relationship between sub-functions and components determines the product's architecture.

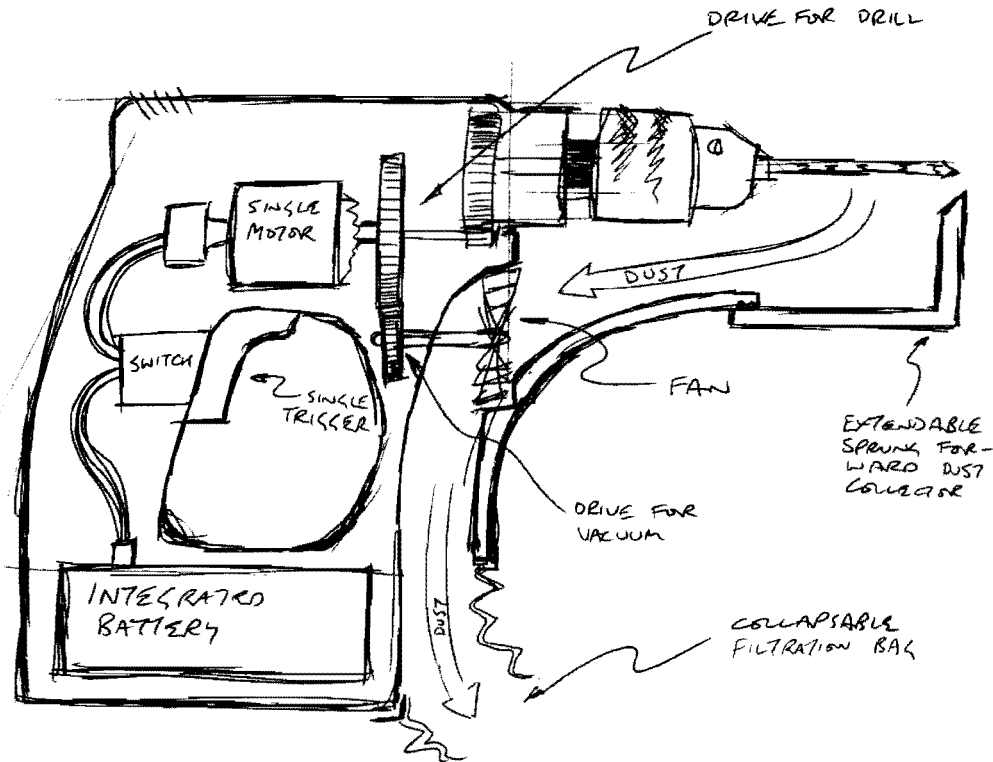
[10%]

(c) Solutions should consider the distribution and conversion of energy, the creation of the hole and the collection of the dust. For example:



[20%]

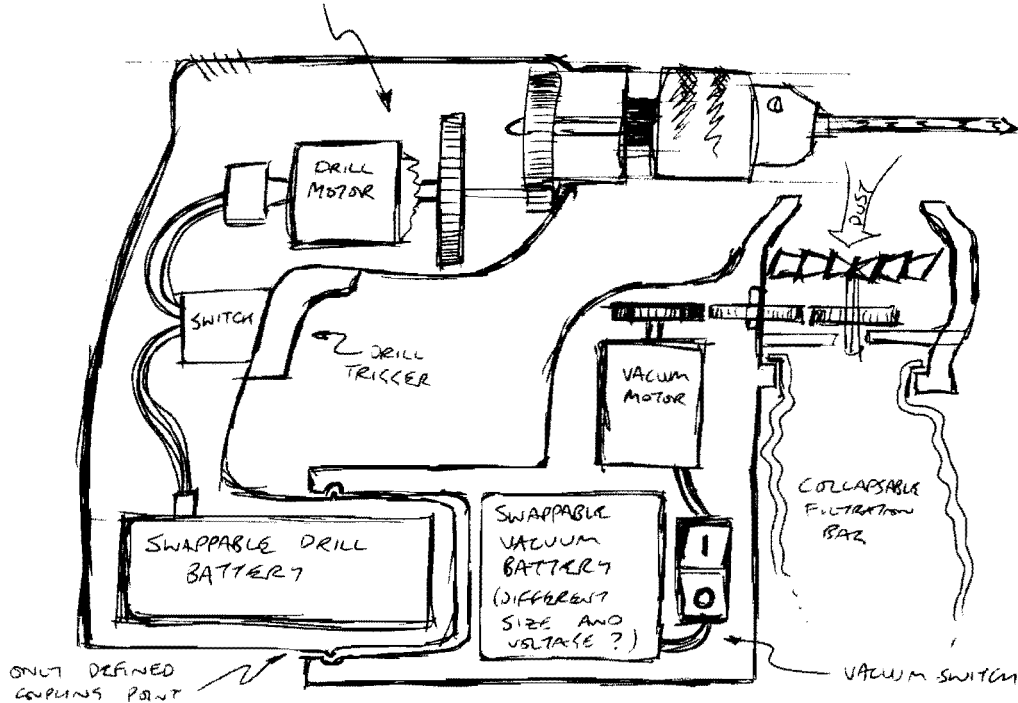
(d) With a highly modular product architecture, we might expect separate systems for the drilling the hole and collecting the dust. This could potentially involve different power supplies, different motors and different housings. With a highly modular architecture, any given module completely performs one or more functions. For example:



[20%]

(e) With a highly integral product architecture, we might expect shared components for the drilling the hole and collecting the dust. This could potentially involve a common power supply, a common motor and a common housing. For a highly integral architecture, any given function may be performed by more than one module. For example:

DRILL IS AN INDIVIDUAL MODULE



[20%]

(f) With a highly modular product architecture, the following benefits might be realised:

- The design of each module can be assigned to a different team in the knowledge that that team are entirely responsible for a particular function
- Modifications made to any particular module need not influence the design of the other module
- If a product is failing to perform a particular function it is clear what module requires replacement or redesign
- Product ranges cost less to manufacture because of commonality between components and interfaces.

With a highly modular product architecture, 'product variety' can be efficiently increased, including variations in performance, features, dimensions, and localisation. 'Product change' is also easier to implement, including changes like upgrades, add-ons, adaptations and replacing consumables.

With a highly integral product architecture, the size, mass, material usage and general performance of the product can be optimised. However, the following penalties might be expected:

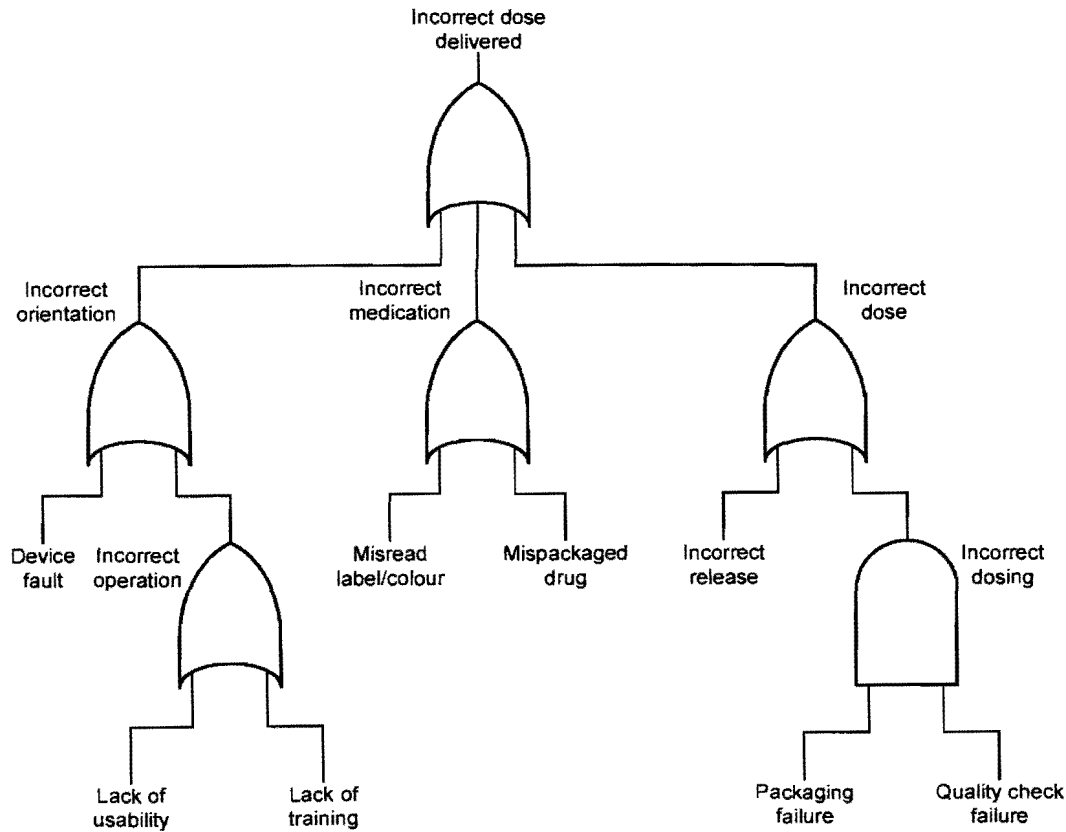
- Assigning modules to teams is difficult because a close coordination between different teams will be essential.
- Changing the design of any one module may necessitate the redesign (or at least the review) of other modules.
- Products that are failing to perform a particular function may necessitate the servicing or redesign of many different modules
- Product ranges cost more to manufacture because many of their components are unique. [20%]

Examiner's comment:

This was a very popular question. (a) A small but disappointing number of candidates were unable to draw a satisfactory diagram of the overall function of the system despite the attention to this in the course (in 4C4 and elsewhere). (b) The majority did well here, but again, a small but disappointing number of candidates were unable to clearly distinguish functions from components. (c) Most candidates developed useful function structures but with some candidates failing to ensure that this was consistent with their answer to part (a). (d) and (e) Many candidates produced sketches that were difficult to read and that were not very different from each other. Lots of opportunities to differentiate the product architectures were missed. (f) Most candidates provided text book answers to this question, covering the many differences between the types of product architectures presented in parts (d) and (e).

- 3 (a) There were a number of issues raised in the lectures that included:
1. Reference to risk management as a means to drive the design process by identifying areas of high risk (show stoppers) which should be investigated in preference to low risk areas. Functional prototyping and engineering models can contribute to risk reduction.
 2. General approach to define function, form, then the means of production, with reference to active risk assessment to identify potential technical and design process problems, and to define risk reduction priorities.
 3. Use of the waterfall model as an example of a verification/validation led approach. Importance of validation of requirements as a precursor to design and the timely use of verification to identify problems early.
 4. Application of a formal approach to prospective hazard analysis during the development of the product.
 5. Reference to the rework model and the resulting need to maximise design quality and reduce delays in the discovery of rework.
 6. Involvement of users in the design, and specifically verification, process. [40%]
- (b) Key requirements might include:
1. Accurate dosing - i.e. effective release of a discrete doses.
 2. Direction of powder into the user's airstream during inhalation.
 3. Provision of a cover for key components that contact the patient's mouth.
 4. An intuitive (fail safe) operation sequence.
 5. Provision for device cleaning.
 6. The appropriate use of food-grade materials.
 7. Provision of a remaining dose counter.
 8. Appropriate colour coding for difference medications. [20%]
- (c) There are a number of appropriate approaches that might include:
1. The requirements list should be validated with users and healthcare providers to ensure that it represents a description likely to lead to a device that is 'fit for purpose'.
 2. The design process should be constructed to develop and test high-risk design elements first, for example, the development of the dose release systems.
 3. Early involvement of users in the form design and operation sequence appraisal could reduce use errors and improve usability.
 4. Formal verification experiments will be required to prove the quality and reliability of the device, particularly its ability to provide the correct dose through a typical lifetime of use.
 5. Formal user trials will likely be required to prove that the device performs as intended in delivering an effective drug dose to the user. [20%]

(d) The 'top event' for the fault tree might be "Incorrect dose delivered". There are then many possible forms for a fault tree, dependent on the way in which the device operation and manufacturing are viewed. One such tree is shown below. Most of the logic gates in the tree are likely to be OR gates except where checking systems may also have to fail for incorrect operation, then AND gates may be present.



[20%]

Examiner's comment:

A popular question requiring discussion on risk management based on a novel drug delivery device. Part (a), generally answered well, allowing much scope for candidates to display their knowledge of a range of risk management thinking. (b) Generally answered well, but often lacking in-depth thought about the new device. (c) A range of answers with the best describing verification and validation in principle and then with reference to the new device. (d) Most candidates were able to draw the fault tree, with the best providing good insight into potential failures.

4C4 DESIGN METHODS Crib 2012

4(a) There is a need to compute the accept/reject rates for each pack type and multiple by the incidence of each type in the batch. Deviations are computed assuming 6σ is equal to the range of the weight and that for a pack all variations are random and the deviation scales by the square root of the pack size.

With the check weight set at 495g, and the tolerance per parts at $\pm 1g$, using the probabilistic calculation is as in the notes, 168 good product will be rejected and 1 short pack accepted per batch.

ORIGINAL SETTINGS

	no	batch	wt (g)	+/- (g)	mean (g)	stdev (g)	chk (g)	z	f(z)	accept	reject	total
1 piece	1		10.00	1.00	10.00	0.33	495.0					
50 pieces	50	9,899	500		500	2.36		-2.12	0.9831	9,731	168	9,899
49 pieces	49	100	490		490	2.33		2.14	0.0161	1	99	100
48 pieces	48	1	480		480	2.31		6.50	0.0000	0	1	1
		10,000								9,732	268	10,000

[30%]

(b) Reversing the calculation, with the reject rate of good product set at 1, and the tolerance at $\pm 1g$, the weight limit should be 491.2g, with 29 short packs accepted per batch.

REDUCE CHECK LIMIT

	no	batch	wt (g)	+/- (g)	mean (g)	stdev (g)	chk (g)	z	f(z)	accept	reject	total
1 piece	1		10.00	1.00	10.00	0.33	491.2					
50 pieces	50	9,899	500		500	2.36		-3.72	0.9999	9,898	1	9,899
49 pieces	49	100	490		490	2.33		0.53	0.2975	29	71	100
48 pieces	48	1	480		480	2.31		4.87	0.0000	0	1	1
		10,000								9,927	73	10,000

[30%]

(c) Also reversing the calculation, with the reject rate of good product set at 1, and the weight limit at 493g, the tolerance should be $\pm 0.8g$, with 5 short packs being accepted per batch.

REDUCE VARIATION

	no	batch	wt (g)	+/- (g)	mean (g)	stdev (g)	chk (g)	z	f(z)	accept	reject	total
1 piece	1		10.00	0.80	10.00	0.27	493.0					
50 pieces	50	9,899	500		500	1.88		-3.72	0.9999	9,898	1	9,899
49 pieces	49	100	490		490	1.86		1.61	0.0538	5	95	100
48 pieces	48	1	480		480	1.85		7.04	0.0000	0	1	1
		10,000								9,903	97	10,000

[20%]

(d) Reducing the incidence of short packs by 50%, leads to a corresponding reduction in accepted short packs. With no change to the weight limit or tolerance the incidence of accepted short packs is directly proportional to their incidence in the batch (for small numbers).

REDUCE PLACEMENT ERROR

	no	batch	wt (g)	+/- (g)	mean (g)	stdev (g)	chk (g)	z	f(z)	accept	reject	total
1 piece	1		10.00	0.80	10.00	0.27	493.0					
50 pieces	50	9,949	500		500	1.88		-3.72	0.9999	9,948	1	9,949
49 pieces	49	50	490		490	1.86		1.61	0.0538	2	48	50
48 pieces	48	1	480		480	1.85		7.04	0.0000	0	1	1
		10,000								9,950	50	10,000

If the incidence of short packs cannot be reduced a 'good' solution, with 1 good pack rejected and 1 short pack accepted can be obtained if the check weight is set to 493.5g and the tolerance to $\pm 0.7g$.

[20%]

Examiner's comment:

The least popular question on the paper, despite being based on a relatively simple example, similar to one in the notes. This question required candidates to analyse a range check-weighing solutions using a probabilistic approach. Part (a), most candidates had a good sense of direction, but also ended up with the wrong answer, most often due to erroneous assumptions relating to the standard deviation of the pack and its relationship to the standard deviation of the part. (b) The reverse problem to (a) was generally done less well, with similar erroneous assumptions. (c) Generally answered well by those who had got this far. (d) Various vague answers with a few identifying the underlying relationship.