Validation of cold storage shelves in an automated dispensing system

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- OBJECTIVE — To establish whether the cold storage shelves of a ROWA Speedcase tandem system consistently provide a suitable storage area for pharmaceuticals that need to be stored at a temperature between 2 and 8C. To determine whether the LCD display provides an accurate and reliable indication of the temperature achieved. To establish whether heat generated by the system (including automatic loaders) effects the ambient temperature in the areas where drugs are being stored.
- METHODS — Calibrated temperature data loggers were used to establish the temperature pattern in the cold storage areas before and after stocking the robot and during its use. The ambient temperature in other areas of the robot and surrounding the robot were similarly assessed.
- RESULTS — After adjusting the settings in some scenarios, it was possible to maintain the cold storage areas of the system at 2–8C. Temperatures in the non-cold storage areas ranged from 23 to 27C.
- CONCLUSION — The cold storage shelving has been validated, to prove its suitability for refrigeration of pharmaceuticals. However, it would be useful for the LCD temperature display to be to one decimal place (rather than displaying whole numbers). The ambient temperature in areas close to the robots is higher than that in the rest of the dispensary. Steps should be taken to manage this.

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Automated dispensing is becoming firmly established in the UK, with systems having been installed in several hospital dispensaries. To date, most hospitals have chosen the ROWA Speedcase system, supplied in the UK by ARX.[1] This is available in a variety of configurations, with a range of "optional extras", including automatic loaders, in-line labellers and cold-storage shelving.

At the Freeman Hospital, part of the Newcastle Hospitals NHS Trust, we too purchased a ROWA Speedcase (tandem configuration). Among the extras we bought were two cold-storage areas (power input 430W/2.65A, refrigerating capacity 750W at 20C and relative humidity of 40 per cent, air intake 0.45m/h by 20 Pascals). The cold storage shelves are located within a fixed area of each robot and are contained in a closed system. The door to them opens either to put stock away or to remove items for dispensing — see Figure 1, p373.

Cold-chain products used at the Freeman Hospital (and others) need to be stored in the temperature range 2–8C. We therefore set about validating the temperature in the cold-storage units, to show that they were suitable for storing cold-chain pharmaceuticals. We also assessed the accuracy of the LCD temperature display provided by the manufacturers.

Other pharmaceutical products should be stored at a temperature not exceeding 25C. We therefore thought it appropriate to assess the temperature in the robot and in the dispensary, particularly since we also chose to install two "Pro-Logic" automatic loaders, which might potentially affect the ambient temperature.

Methods

Throughout the assessments, the data loggers used were Comark Evolution N101. These contained an encapsulated probe and were supplied with a calibration certificate (confirming their accuracy to +/– 0.5C). They had been in use in the pharmacy department at the Freeman Hospital for less than one year.

Cold shelving assessments Assessing the cold-chain storage facilities involved positioning five data loggers at regular intervals in the shelving spaces. Three sets of measurements were taken:

- Assessment of areas (unstocked, with doors closed) shortly after the robots had been installed. The temperature was logged every five minutes for a one week period in each cold storage unit.
- Assessment of areas (unstocked) simulating a busy clinic day. The "roll up" door to the cold storage area was manually opened four times every five minutes for a 2h period. The temperature recorded on the integral LCD display, positioned on the exterior of the robots, was also recorded.
- Assessment of areas in use (ie, once the robots had been filled with stock and time had been allowed for a temperature equilibrium to be reached. Shelf positions were blocked off, using the computer software, to prevent the robot allocating stock to the space taken up by the logger). The cold storage area was monitored every 10min for a period of one week. Temperature readings from the LCD display were also taken.

The highest or lowest extreme (as appropriate) of the five data logger readings was used as the measurement. Where the initial set of measurements recorded temperatures outside of the 2-8C range, adjustments were made to the cold storage unit settings. In addition, where there was initially a poor correlation between the temperature recorded using the data loggers and the LCD display, adjustments to the LCD calibration was made.

Ambient conditions assessment. Two sets of temperature assessments were made:

- Inside the robot at its four corners (positions A,B,C and D on Figure 1, p373) to enable comparisons both within and between the robots to be made.
- Outside the robot, in the automatic loading area (position E on Figure 1) and in the dispensary area, furthest away from the robots (beyond the dispensary workstations on Figure 1).

After an initial evaluation of the results, it was decided to simulate the journey of a stock item from receipt in the dispensary to being placed on a shelf within the robot, to determine the mean amount of time an item remains in the "warm area." A logger was

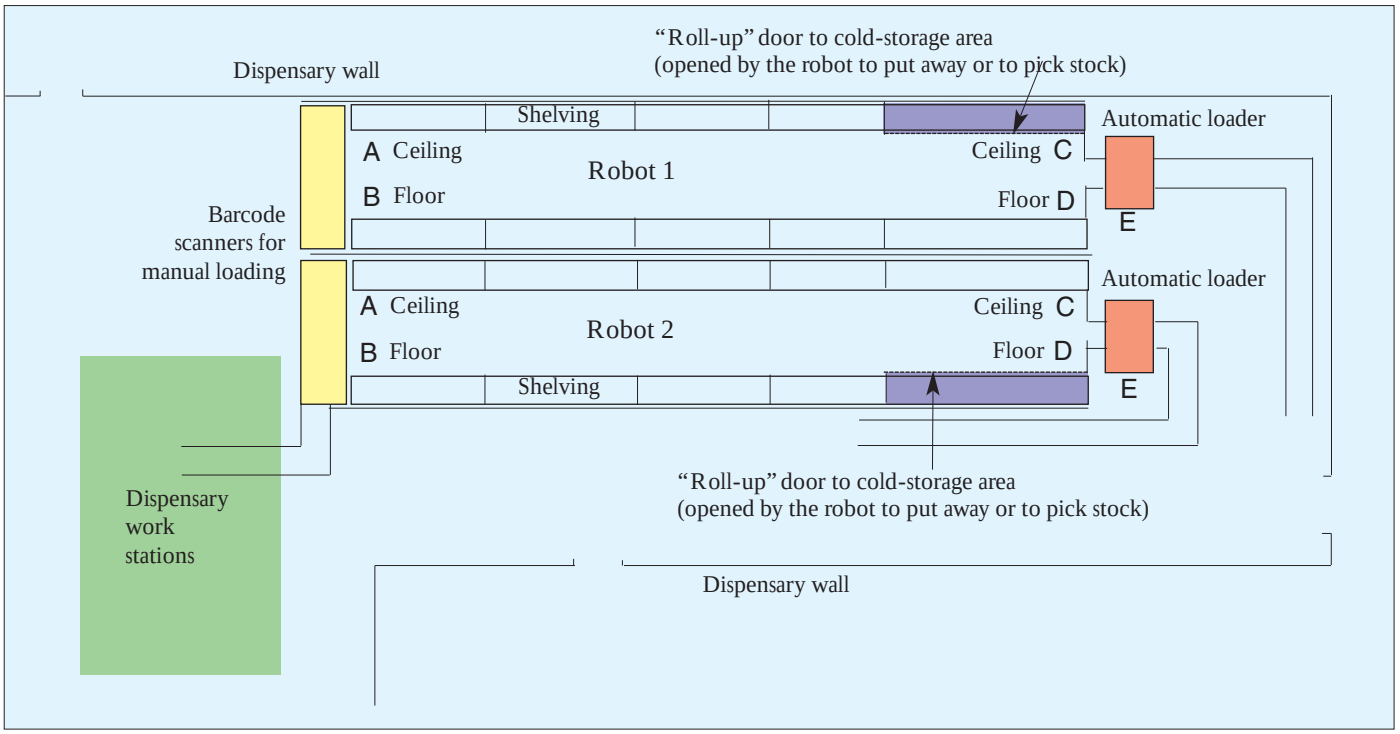

Figure 1. Diagram showing the layout of the robots in the dispensary at the Freeman Hospital

packed as a pharmaceutical, given a bar code, and subjected to the same processes as any other item being loaded into a robot. Journey time was recorded (using a stopwatch) from the time it was received in the dispensary to the time it was placed in a robot. This measurement was made twice, for each robot.

Airflows within the robot Air current tubes (ie, "smoke pens", Drager CH 00216) were used to generate smoke inside each robot, which was tracked (by eye) as it circulated.

Results

Cold shelving assessments The maximum and minimum temperature found in the cold storage areas are set out in Table 1 (p374). Figure 2 (p374) shows the degree of correlation achieved between the temperature recorded by the data loggers and that shown on the LCD display after adjusting the LCD settings.

Ambient conditions assessment The minimum and maximum temperatures recorded in the non-cold storage areas of each robot are set out in Table 2 (p374).

Outside the robots, the minimum and maximum temperatures recorded in the automatic loading area were 24.8C and 26.9C, respectively, and those recorded in the dispensary were 21.2C and 23.4C, respectively.

The simulation of the journey of a stock item showed that it took an average (mean) of 65 minutes for an item of stock to be put away after a load had been tipped into the hoppers of the automatic loaders.

Airflow assessment It was not possible to generate a sufficient volume of smoke to track its path while inside the robot, and so the results of this assessment were inconclusive.

Discussion

The assessment of the cold storage shelves shortly after installation (unstocked, with the door to them remaining closed) confirmed that the temperature in these areas was suitable for storing cold-chain pharmaceuticals. Even so it was decided to adjust the settings in Robot 2, since the initial recordings reached (although did not exceed) the maximum allowable temperature of 8C.

The assessment simulating a busy clinic day corresponded to a total of 84 openings over a 2h period. This was more than the maximum amount of openings of 72 that would generally be required — ie, if 12 patients each required six containers of an item stored in the refrigerator (eg, erythropoietin). The results showed that there was a gradual increase in temperature gradient over the "busy clinic" period (graphs not reproduced), although, after altering the cold-storage unit settings, it was possible to ensure that the range of 2–8C was maintained. The upper level did reach 8C, but did not exceed it. The fact that the temperature reached 8C was presumably less of an issue when the shelves were stocked, because the products themselves would not heat as fast as the air around them and would therefore be likely to remain safely within the temperature range.

Figure 2 (p374) shows that, after adjustment, it was possible to achieve a good degree of correlation between the temperature shown on the LCD display and that recorded from the warmest shelf in each cold shelving unit.

A shortcoming with the robots as installed is that each LCD display only provides a single reading for one part of each cold storage unit. It would be desirable for several probes to be included in the cold-storage areas and at least one in the ambient temperature section. Also the readings on the LCD display do not show decimals. It would be desirable to be able to read the temperature to at least the nearest 0.5C (ie, the accuracy of the data loggers), and ideally to the nearest 0.1C.

When simulations of the robot in use were carried out, there was poor correlation between the actual temperature recorded with the data loggers and the temperature shown on the LCD display for Robot 1 — the LCD display showed the temperature to be approximately 2C warmer than it actually was — and so the LCD display was adjusted accordingly. It was noted that no adjustments were necessary for Robot 2. This might be because Robot 2 has one long side facing onto the dispensary, while Robot 1 has a long side against a wall, which presumably provides some insulation. However, if this were to be the reason, it is not clear why the same poor correlation in Robot 1 was not noted when a busy clinic was simulated.

The Freeman Hospital was the first UK hospital to have automatic loading equipment installed. Data loggers, placed at the four corners of each robot, showed that a temperature gradient was present. Predictably, the top of the robot (points A and C on Figure 1) was the warmest area, but the

Table 1: Maximum and minimum temperatures recorded on the shelves of the cold storage areas of a ROWA Speedcase

Assessment of area supplied by manufacturer	Robot 1	Robot 2
Minimum temperature	3.4	3.8
Maximum temperature	6.9	8.0
Minimum temperature, after settings adjustments made	N/N	2.4
Maximum temperature, after settings adjustments made	N/N	6.2
Assessment simulating a busy clinic day		
Minimum temperature	2.4	1.5
Maximum temperature	8.5	6.2
Minimum temperature, after settings adjustments made	2.1	3.2
Maximum temperature, after settings adjustments made	8.0	7.9
Assessment of area in use		
Minimum temperature	3.3	2.3
Maximum temperature	7.9	7.5
Minimum temperature, after settings adjustments made	N/N	N/N
Maximum temperature, after settings adjustments made	N/N	N/N

"N/N" means that adjustment was not necessary because initial readings were in the 2–8C range

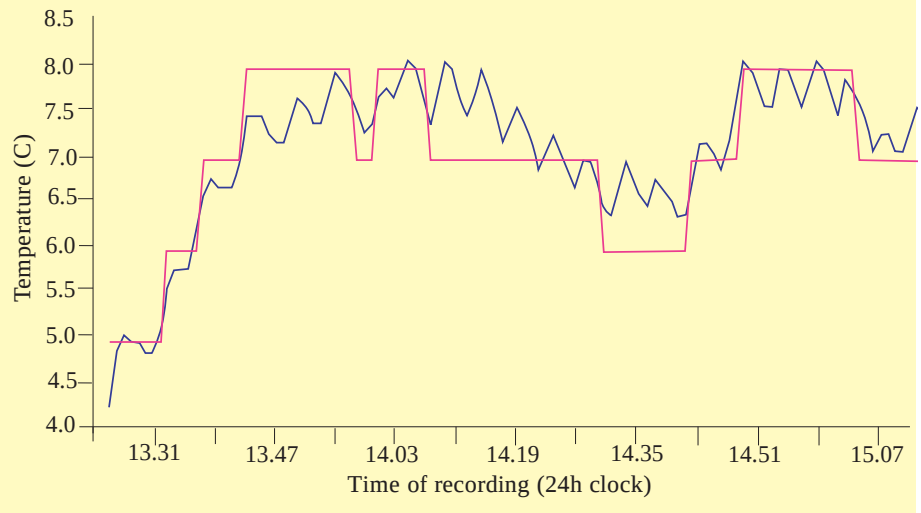

Figure 2. Graph showing the correlation between the temperature of the warmest shelf recorded using data loggers (blue line) and the temperature displayed on the LCD (red line) for Robot 1. A similar degree of correlation was achieved for Robot 2.

back (points C and D, the area containing the entrance for stock from the automatic loader) was cooler than the front of the robots. It was therefore concluded that the automatic loaders had no detrimental effect on the ambient temperature inside the robots.

The maximum ambient temperatures were found to be in excess of 25C inside the robots. The monitoring was performed in high summer and therefore presented a worst-case scenario. Consideration, by manufacturers of automated dispensing systems, should be given to the requirement for temperature monitoring. A system of probes to allow readings from various areas inside the robots (as well as the cold shelves) would be a significant improvement.

Ambient temperature recordings showed that the area outside the robot around the automatic loading devices was warmer than the rest of the dispensary. This heat gain was thought likely to result from the loaders exuding heat during operation, primarily because they have internal lights. Further monitoring (data not shown) confirmed that temperatures increased when the loaders were switched on, not only in the surrounding area, but also in all areas of the dispensary. However, even when the loaders were not in operation, there was still a temperature difference between the different areas of the dispensary, suggesting that other factors, such as the presence of the robots themselves, contributed to temperature increases. It should be noted that, according to the manufacturer, the internal lighting is integral to the operation of the loaders, because it is needed by the camera to assess the dimensions of a pack before it is put away. The system is designed to switch off the light as soon as the last pack is loaded. In the short-term at least, it has been decided, pragmatically, that about 65 minutes is an acceptable time for a non-cold chain pharmaceutical product to be exposed to the temperatures in and around the automatic loaders. (Cold-chain items are manually loaded using the barcode scanners, with the putting away of these items now taking precedence over those that are automatically loaded).[1] Ways of reducing the temperature (eg, air conditioning) might need to be investigated if, for example, the system were to be used overnight to prepare ward stock boxes, in which case the average "journey time" could significantly increase.

Conclusion

It is possible to validate the cold storage shelving of the ROWA Speedcase to prove its suitability for pharmaceuticals refrigeration. Adjustments by the manufacturers to the equipment design would improve temperature recording — the LCD temperature display should show a reading accurate to at least the nearest 0.5C, and preferably 0.1C, and a multi-channel probe system should be included. The ambient temperature in and around the robots is higher than that in the rest of the dispensary. Steps should be taken to manage this higher temperature.

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References

1. Brice S, Hardy L, Longshaw R. Evaluation of automatic loading devices with a ROWA Speedcase. Hospital Pharmacist 2006;13:375.

Table 2: Maximum and minimum temperatures (C) recorded in the non-cold storage shelves of the ROWA Speedcase

	Robot 1	Robot 2
Position A		
Minimum temperature	26.7	26.0
Maximum temperature	27.7	26.9
Position B		
Minimum temperature	23.1	23.8
Maximum temperature	23.7	24.2
Position C		
Minimum temperature	23.8	24.3
Maximum temperature	24.8	26.5
Position D		
Minimum temperature	22.5	23.0
Maximum temperature	23.5	24.1