Kaplan Medical Centre (KMC) and Beth-El Zikhorn Yaqov Industries Ltd (Beth-El) have developed the IsoArk, a collapsible negative pressure isolation chamber that is specifically designed for intensive care situations, and carried out preliminary clinical testing of the chamber. The safety and feasibility of treating contagious patients in real-life conditions was investigated.

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Introduction
Emerging infectious diseases, “classical” highly infectious agents like aspergillosis and tuberculosis are health threats both for the general public and the healthcare providers. Airborne Infection Isolation Rooms (AIIRs) are part of the arsenal of containment and infection control measures for airborne transmissible agents.

In many major cities, hospitals are often at maximum capacity. The extent of the need for AIIRs during a natural outbreak of airborne-transmissible disease, such as severe acute respiratory syndrome (SARS), is anticipated to be very high. For example, during a few months of the 2003 global SARS epidemic, the National University Hospital in Singapore had to isolate roughly 600 patients in negative pressure conditions [1]. Temporary negative pressure isolation rooms were used as emergency room triage units [2]. Shortage of AIIRs was even worse in Toronto, Canada, where the city’s healthcare infrastructure was overwhelmed with 253 cases, 43 deaths and 27 000 exposed persons, including healthcare workers [3]. Any healthcare system has only limited number of AIIRs and lacks the patients’ isolation capacity to handle a significant event [4]. Fixed AIIRs are not only costly to build, but they require appropriate maintenance procedures. Intensive care treatment is associated with aerosol-generating procedures, thus increasing the risk of contagion for the staff of the intensive care unit (ICU), for other patients and the hospital in general. Furthermore, the existing fixed AIIRs are not always suited for intensive care treatment of isolated patients. There is thus a need for a cost-effective, highly flexible operational concept of a portable AIIR with intensive care capabilities that can be rapidly erected in many areas in any hospital, and in extreme situations even in makeshift healthcare facilities.

Methods
The development and testing process of the portable isolation chamber comprised the three following stages:

1. Constructing an IsoArk prototype within the general ICU of KMC, modifying it according to ICU environmental and operational standards and needs.
2. Following intensive briefing and training for the ICU personnel, the efficacy and safety of the chamber were tested by measuring environmental parameters, first without, and later with, continuous actual care of three patients for 48 hours each. The physicians and nurses worked in personal protective equipment (PPE) used for airborne precaution and provided ICU procedures’ care, including standard minimal invasive procedures.
3. Testing the feasibility of erecting the chamber in a non-ICU environment.

General description of the isolation chamber
As a result of suggestions made by the end-users in stages 1 and 2 of the testing process, the construction underwent some modifications as follows: the system consists of a main chamber and an integrated airlock (Figure 2). The overall size of the main chamber in the prototype tested was 3.05 m x 3.81 m x 2.30 m. The skeleton is based on a light metal frame. No floor covering is used, but a double seal attached to the bottom portion of the liner provides a seal with the floor through the negative pressure inside the chamber and the weight of the framework. The walls and ceiling are made of non-permeable, deterrent- and disinfectant-resistant, fire-retardant single-layer PVC. The plastic is transparent, allowing observation into the contained environment from the outside and minimising confinement sensation. Curtains hang on the outside provide privacy when needed.

Tool conduits in the sidewalls of the main chamber provide access for probes, hoses and cables for supply and data support systems, minimising the need for equipment decontamination and disposal. Cables that are leading to panels with electricity and medical gas ports hang on an inner skeleton, providing support to equipment within the chamber. An interchangeable window offers access to a chest X-ray machine or provides glove-box access for routine checks and management of the patient. The chamber is separated from the outside by an airlock with wide double swingdoors. The filtration unit automatically switches to a high flush mode for an adjustable amount of time when someone enters the airlock, maximising protection while minimising delay when leaving the chamber. One of the walls has an opening into a patent container for contaminated laundry, used PPE and other contaminated material.

A single, independent filtration unit creates three stages of airflow:
1. “Night” mode with an airflow rate of 1000 m3/hr,
2. “Day” mode with an airflow rate of 1400 m3/hr, and
3. “Airlock flushing” mode with 2200 m3/hr (automatically initiated upon entrance to the airlock) providing up to 1000 air exchanges per hour depending on the airflow.

A pre-filter and a high efficiency particulate air (HEPA) filter provide a minimum filtration efficiency of 99.995%, as required by the EN-1822 standard. An ultraviolet (UV) radiation unit is incorporated in the filtration unit. The latter contains audiosual alarm systems and visual information concerning the pressure gradient between the chamber and the external world.

Objective safety parameters collected throughout the experiment inside and outside the isolation chamber included air temperature, humidity, noise, CO₂ and O₂ concentration levels, as well as pressure gradients. Pre-defined safety levels were CO₂ > 3% and O₂ < 18%.

Results
The portable AIIR was constructed within the ICU by three Beth-El technicians in approximately 45 minutes. The patient’s bed and all necessary equipment were wheeled in subsequently. Maximal temperature and humidity levels in the first experiments were 24.2°C and 53% respectively. No breach of CO₂ and O₂ safety levels were observed in all testing.
Efficacy parameters (Table 1)
Maximal in-chamber CO₂ levels measured were 320 ppm (empty chamber) and 339 ppm (chamber occupied by a patient and a member of staff). Minimal O₂ levels were 20.6% and 20.2% respectively. Maximal noise levels were 65dB when empty and 62dB when operational. (Note: the overall environmental noises of the total ICU were also picked up and calculated in this figure. Refer to Table 1 for the noise level of the unit). The maximal noise level delta was 7 dB, i.e. noisier outside the chamber than inside!

Subjective assessment
On a scale of 1 to 10, the ICU staff graded their subjective preliminary experience with the portable AIIR as follows (average values):
* ease of breathing in the main chamber = 6.2
* freedom of claustrophobic sensation = 6.8
* noise level = 3.3
* ease of external communication = 3.5
* ease of internal communication = 7.8
* general access to patient = 6.5
* ease of providing medical care = 8.1
* ease of invasive procedures = 7
* washing the patient = 7.8
* making the patient's bed = 8
* suctioning the patient = 6.8
* visual contact with the monitor = 6.3
* control of the respirator = 8.3
* control of the infusion pumps = 7.9
* ease of moving inbound through the airlock = 8.2
* moving outbound = 8.6
* using PPE within the airlock = 7
* passing through the airlock: laboratory samples = 7.7
* laundry = 7.6
* a visitor = 7.1
* using waste disposable unit = 7.6

Additionally, many nurses pointed out that the increased level of stress and operational constraints while working inside an isolation room call for reinforcement of the nursing staff.

Basic operational feasibility in a non-ICU setting
The AIIR was erected in the physical therapy gymnasium. This place is already equipped to serve as an alternative ICU in case a surge capacity is needed. In less than 45 minutes the isolation chamber was operational.

Discussion
The AIIR was incorporated in the ICU environment without posing safety problems to patients or healthcare providers as observed or measured during field testing. As learned during the SARS epidemic, it is recommended that nursing manpower be strengthened to accommodate the greater stress and efforts resulting from working in full PPE inside the AIIR. Further technical improvement considered are a two-way communication system, the inclusion of a hand-disinfecting unit inside the airlock, and adding external patient monitors. Other portable units were developed, but none were oriented for intensive care treatment and no field testing has been done.

Safety parameters (Table 1)
Maximal in-chamber CO₂ levels measured were 320 ppm (empty chamber) and 339 ppm (chamber occupied by a patient and a member of staff). Minimal O₂ levels were 20.6% and 20.2% respectively. Maximal noise levels were 65dB when empty and 62dB when operational. (Note: the overall environmental noises of the total ICU were also picked up and calculated in this figure. Refer to Table 1 for the noise level of the unit). The maximal noise level delta was 7 dB, i.e. noisier outside the chamber than inside!

Maximal in-chamber humidity measured when operational was 24°C and maximal delta temperature in those conditions was 1°C. Maximal in-chamber humidity measured was 7 dB, i.e. noisier outside the chamber than inside!

Table 1. Safety parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Chamber empty</th>
<th>Chamber operational</th>
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<tbody>
<tr>
<td>Minimal temperature (°C)</td>
<td>23.2</td>
<td>23.2</td>
</tr>
<tr>
<td>Maximal temperature (°C)</td>
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<td>24.2</td>
</tr>
<tr>
<td>Minimal delta temperature (°C)</td>
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<tr>
<td>O₂ (%)</td>
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<td>20.2%</td>
</tr>
<tr>
<td>CO₂ (%)</td>
<td>320 ppm</td>
<td>339 ppm</td>
</tr>
</tbody>
</table>

Table 1. Safety parameters

As early as 1993, Marier and Nelson laboratory-tested an isolation unit, which was not collapsible or truly portable [5].

Conclusion
The AIIR, a rapidly collapsible AIIR was developed and preliminary field-tested both in a general ICU and in a non-ICU environment. An AIIR that meets CDC, UL and European standards for safety and technical performance provides a safe medical care environment while protecting the rest of the ICU and the hospital in general. Outside hospitals, the AIIR can be erected in groups on any smooth flat surface with basic healthcare infrastructure (e.g. aboard hospital ships). Providing adequate logistic support, the AIIR can be placed in makeshift facilities, such as military field hospitals, stadiums or other large halls.

The AIIR tested provides a relatively non-expensive surge-capacity and containment solution for emergencies of airborne-transmissible contagious disease. Furthermore, this concept adds flexibility to public health planners on the national and regional levels.

References

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