



Portable Emergency Oxygen and the Role of the R15 Medical Device

Introduction

When was the first time you struggled to breathe? Was it when the air was *knocked out* of you during a sports activity? Did it happen in an instant when you accidentally inhaled water during a swim or perhaps while drinking a beverage too quickly?

These rare and transitory shortness of breath experiences provide some insight into the what occurs during more than **7 million annual medical breathing emergencies** in the United States.ⁱ

The high incidence of medical breathing emergencies is not widely known by the Public – certainly not as well as is cardiac arrest. By comparison, the annual number of cardiac arrests in the United States is about 600,000, or less than 10% the number of breathing emergencies.

Every year the American Heart Association trains more than 12 million people in cardiopulmonary resuscitation (CPR) to help keep blood moving when the heart stops pumping.ⁱⁱ Well over 2.4 million automatic external defibrillators (AED) have been sold in the United States and are now available in public places like airports and shopping malls.ⁱⁱⁱ These medical devices are designed

for use by an untrained bystander to *jumpstart* the heart of a cardiac arrest victim back to life.

Together, CPR training and AED use have helped countless people survive a cardiac arrest. These tools are now part of de facto best practices that are embraced in communities around the Country. Many States now have requirements and recommendations for both CPR training and

“Oxygen is the most commonly used drug in emergency medicine and when used judiciously in the treatment of hypoxaemia it **undoubtedly saves life.”**

Emergency oxygen therapy: from guideline to implementation, Breathe, June 2013, V9, N4

AED availability in public places.^{iv}

Unfortunately, the kind of efforts that have driven bystander assistance for victims of cardiac arrest have not occurred for victims of breathing emergencies.

Thanks to FDA clearance of the R15 Portable Emergency Oxygen device, bystanders can now quickly and safely assist the many victims of breathing emergencies until professional emergency medical services (EMS) arrive on scene.

The Life-threatening Effects of Oxygen Deprivation

Oxygen surrounds us, comprising about 21% of the air that we breathe. Under normal conditions, breathing is an automatic, unconscious act.^v The natural ebb and flow of air into and out of our lungs delivers nourishing oxygen to our blood and organs while carrying away carbon dioxide, a byproduct of cellular activity.

During a breathing emergency, the normal exchange of oxygen and carbon dioxide in the lung is disrupted. This disruption can lower the amount of oxygen in the blood (hypoxemia) and lower the amount of oxygen in organs, including the brain (hypoxia).^{vi} **Breathing emergencies of even a very short duration can be catastrophic to the victim.**

- In less than a minute, victims may experience mild symptoms of dizziness, concentration and coordination.
- In less than three minutes, symptoms can quickly worsen to include confusion, brain swelling and seizures. “When there is also an interruption of blood flow, as after a cardiac arrest, this may lead to damage...like that occurring in a stroke.”^{vii}
- In less than ten minutes victims can succumb to loss of consciousness, coma and death.

Even in cases where victims survive a breathing emergency, they can suffer from lifelong problems with tremors, vision, and severe memory loss.

Following are some examples of the many events^{viii} that can lead to breathing emergencies, hypoxemia and hypoxia:

- Allergic Reaction
- Asthma Attack
- Anemia
- Over Exertion
- Cardiac Arrest
- Drug Overdose
- Heart Attack
- Drowning Victim
- Shortness of Breath (e.g. heat exhaustion, dehydration)
- Carbon Monoxide Poisoning
- COPD Flare Up

“Emergency oxygen can be given for many breathing and cardiac emergencies. It can help improve hypoxia (insufficient oxygen reaching the cells) and reduce pain and breathing discomfort.”

Fact Sheet: Administering Emergency Oxygen,
The American National Red Cross

Some concern has been expressed about creating high levels of blood oxygen (hyperoxia) of those treated with oxygen both in and out of hospitals. Hyperoxia, however, “is not a concern for the relatively short pre-EMS period using Food and Drug Administration (FDA)-approved units intended for first aid, which provide medium concentration oxygen”^{ix} – as is the case with the R15 device.

The rapid delivery of emergency oxygen during a breathing emergency is intended to help maintain adequate levels of oxygen in the blood and organs until professional emergency medical services arrive.

The Role of Portable Oxygen during Breathing Emergencies

In the hospital setting oxygen is piped throughout the facility from the Emergency Room to the patient bedside. Appropriate oxygen uses in this contained setting are achieved by highly trained healthcare professionals.

Outside of the hospital, oxygen has been a tool that was available only to trained personnel. It is not unusual for a community Parks and Recreation Department or local YMCA to offer lifeguard certification through the American Red Cross that includes the proper use of emergency oxygen.^x

“Ideally, individuals who are experiencing opioid overdose should be ventilated with 100% oxygen before naloxone is administered so as to reduce the risk of acute lung injury.”

Opioid Overdose Toolkit:
Five Essential Steps for First Responders,
HHS Substance Abuse and
Mental Health Services Administration

Oxygen is recommended therapy by the American Red Cross for adults, children and infants who are experiencing breathing emergencies, including those who are not breathing.^{xi}

Emergency oxygen may be especially important to address emerging public health issues. “With the increasing prevalence of asthma in schools, as well as anaphylactic reactions to foods, insect stings, inhaled agents...it is important to consider having oxygen as a part of a school’s emergency

response.”^{xii} In cases of opioid overdose while awaiting EMS, bystanders can administer oxygen to victims “before naloxone is administered so as to **reduce the risk of acute lung injury**”.^{xiii}

In public environments such as community pools, lifeguards trained in the use of emergency oxygen have access to pressurized oxygen cylinders like those carried on EMS ambulances. Small and portable, these cylinders must be properly secured for safety reasons. Safety procedures typically include upright storage of cylinders in a secure well-ventilated area, use of a rack to prevent falling, and environmental control of temperature and exposure to direct sunlight. Such storage can delay access to oxygen when needed.

Pressurized oxygen cylinders are restricted to trained personnel like lifeguards and EMS professionals because improper use can lead to significant danger to life and property. Even personnel who are trained in proper use of pressurized oxygen cylinders can make dangerous mistakes.

In one reported incident an oxygen cylinder flashed and set an emergency medical technician on fire during a routine equipment inspection on her ambulance. The technician’s associates were able to extinguish her fire and save her while the ambulance where the fire started went up in flames.^{xiv}

The risk of pressurized oxygen cylinders to the Public has been a significant obstacle to making emergency oxygen more widely available to victims of breathing emergency. **Now a non-pressurized means to deliver emergency oxygen is available and safe for bystander use.**

The Role of the R15 Portable Oxygen Device

The R15 device is the only commercially available portable emergency oxygen product that is safe to use in public places by untrained bystanders.

The R15 device is cleared by the FDA to deliver oxygen at a therapeutic rate of 6 liters per minute (LPM) for 15-minutes. The R15 device may be used for breathing emergencies as with conventional pressurized oxygen cylinders.

About the size of a small backpack, the R15 device generates oxygen on demand by combining otherwise inactive solid chemicals and so does not offer an explosive risk as do pressurized oxygen cylinders. Due to its safe design, the R15 device may be positioned in a public space just like a basic first-aid kit or AED.

Unlike an AED, the R15 device needs no electric or battery source and no maintenance. It has a 2-year shelf life, at which point it is replaced with a new R15 device.

Instructions are clearly displayed on the R15 device in both words and diagrams so anyone can understand proper use. When a breathing emergency occurs, any bystander can assist the victim in several simple steps:

1. Call 911 to request EMS response
2. Lay the R15 device flat next to the victim and remove the sealing tape to open the breathing mask compartment
3. Rotate the lever on the front of the R15 device to start oxygen flow

4. Place the R15 breathing mask over the victim's mouth and nose and secure with the mask strap

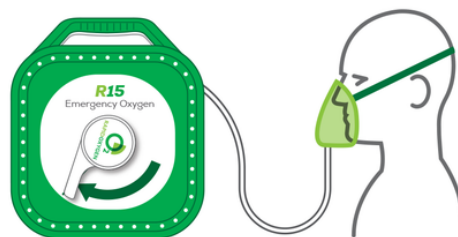


Diagram of the R15 Device in Use

The R15 device may be **easily integrated into existing medical response protocols** that are followed in private settings (e.g. corporate facilities) and public spaces (e.g. community pools, airports, shopping malls, golf courses).

Looking toward the future, the R15 can play a key role in a Unified Station for Emergency Response (USER). The USER model would help ensure that first responders have ready access to a variety of life-saving tools such as:

- Fire Extinguisher
- First Aid Kit
- Automatic External Defibrillator (AED)
- R15 Portable Emergency Oxygen device
- Naloxone^{xv} inhaler for opioid overdose
- Epinephrine^{xvi} auto-injector for allergic reactions

The Future of Portable Emergency Oxygen

Portable emergency oxygen appears to be on an adoption path like that followed by CPR training and AED use. As with CPR and AED, the R15 device enables any bystander to quickly help a victim of a breathing emergency with oxygen.

In addition to providing an additional life support tool to communities, the R15 device may also reduce the liability of facilities that include the device in their emergency medical response protocol.

“Premises liability is a legal concept that typically comes into play in personal injury cases where the injury was caused by some type of unsafe or defective condition on someone’s property.”^{xvii}

The case of Staats versus Vontner's Golf Club is an example of how interpretation of reasonable effort can seriously impact business operations.

According to court documents^{xviii}, "Plaintiff Carolyn Staats nearly died after being attacked by a swarm of yellow jackets while playing golf on a Yountville course operated by Vintner’s Golf Club, LLC (Club). She sued the Club for general negligence and premises liability, but the trial court granted summary judgment against her on the basis that the Club owed no duty to protect its patrons from yellow jackets that came from an undiscovered nest on the course."

The California Court of Appeals reversed the decision noting that, "We hold that the duty of golf course operators **to maintain their property in a reasonably safe condition** includes a duty to exercise reasonable care to protect patrons from nests of yellow jackets on the premises."

The Staats case raises important legal questions about how a court may determine the responsibility of a firm based on the availability of tools like the R15 device.

Conclusion

Oxygen delivered quickly by a bystander during a breathing emergency can offer victims additional life support before EMS arrives on scene.

The R15 device is designed to eliminate the potential safety issues of conventional pressurized oxygen cylinders, and the R15 device should be placed in public areas for rapid access by bystanders.

Cleared by the FDA, the R15 device will provide therapeutic levels of oxygen for 15 minutes which is **about twice the average time** it takes for EMS to arrive on scene.^{xix}

The R15 device complements other important tools in the Public space that are available for bystander use to help improve outcomes of medical emergencies.

For more information, please visit
www.rapidoxygen.com



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