# Viability Assessment Probe for Kidney Transplants

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## Introduction

- Organ transplantation is a procedure where a failed or diseased organ is replaced with a donated working organ.
- Approximately 3500 donated kidneys in the United States are discarded each year.
- Nearly 5000 people in the United States die while waiting for a kidney transplant.
- 156,089 kidneys have been recovered in the United States between 2004 and 2014, of which 27,987 (17.9%) have been discarded.
- Long term survival is greater in patients that receive kidney transplants as compared to patients on long term dialysis.

## Limitations of Existing Solutions

<table>
<thead>
<tr>
<th>Viability Biopsy</th>
<th>Kidney Donor Profile Index (KDPI)</th>
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</thead>
<tbody>
<tr>
<td>Tissue sample may be unrepresentative.</td>
<td>KDPI based on:</td>
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<tr>
<td>Not conducted by renal pathologist.</td>
<td>Donor age, Height, Weight, Ethnicity, History of hypertension, History of diabetes, Cause of death, Serum creatinine, Hepatitis C virus status.</td>
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<tr>
<td>Accounts for about 40-50% of all kidneys discarded in the United States.</td>
<td>Donation after circulatory death.</td>
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- Based only on preretrieval factors that may not be contemporaneous.
- Narrow range of viability that leads to higher discard rates of kidneys.
- Lack of consistency in predicting organ performance post transplant.

## Device Specifications and Application

- Use of machine perfusion (MP) instead of static storage improves short term transplantation outcomes.
- MP can be used as method to assess kidney viability.
- Tissue oxygenation has been found to be a viable method of assessment of organ quality.
- Near Infrared Spectroscopy (NIRS) is a non-invasive method used to monitor oxygenation in tissues.

### The objective of this project is to develop a prototype NIRS probe suitable for blood oxygen monitoring of potential kidney transplants.

### Requirements

- **Sensor Size:**
  - The size of the probe sensor should have dimensions smaller than 11cm by 5cm (size of kidney).

- **Easy Manipulation by Surgeon:**
  - The handle should have a minimum length of 21.6cm.

- **Compatibility with NIRS:**
  - No restriction in the path of light, wireless communication, the sensor must lie perpendicular to the surface of the kidney and contain the sensor.

- **Compatibility within Surgical Environment:**
  - Compatible to use within a sterile bag in a surgical environment.

### Constrains

- **Size of the Container:**
  - The sensor should reach the kidney at a depth of 30.5 cm.

- **Compatibility within Surgical Environment:**
  - Compatible to use within a sterile bag in a surgical environment.

## Impact

- There are no current technologies that can be used to assess the quality of a donated kidney that are commercially available.
- Establishes a new system of assessment and by reducing discard rates of kidneys especially by diseased donors-potentially adopted by entire transplant community.
- **U.S is the largest market for transplants in the world and the market size is expected to grow to $895.2 million by 2024.**
- Helps reduce mortality in patients suffering from chronic kidney disease and failure.
- The average cost for a kidney transplant in the U.S is about $414,800 due to a lack of supply, which could be reduced significantly using this system of assessment.
- **Current prototype can be used by transplant surgeons** to assess differences between a variety of donated kidneys.

## References