

|                 |          |          |          |          |
|-----------------|----------|----------|----------|----------|
| Single Channel: | HCPL0452 | HCPL0453 | HCPL0500 | HCPL0501 |
| Dual Channel:   | HCPL0530 | HCPL0531 | HCPL0534 |          |

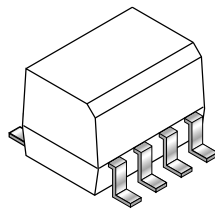
## DESCRIPTION

The HCPL05XX, and HCPL04XX optocouplers consist of an AlGaAs LED optically coupled to a high speed photodetector transistor housed in a compact 8-pin small outline package.

A separate connection for the bias of the photodiode improves the speed by several orders of magnitude over conventional phototransistor optocouplers by reducing the base-collector capacitance of the input transistor. The HCPL04XX devices do not have the base bonded out to a lead for additional noise margin. The HCPL053X devices have two channels per package for optimum mounting density.

## FEATURES

- High speed – 1 MBit/s
- 15kV/ $\mu$ s minimum common mode transient immunity at  $V_{CM}=1500V$  (HCPL0453/0534)
- Open collector output
- Guaranteed performance over temperature: 0°C to 70°C
- U.L. recognized (File # E90700)
- VDE0884 recognized (file#136616)
  - approval pending for HCPL0530/0531/0453
  - ordering option V, e.g., HCPL0500V
- BSI recognized (file# 8661, 8662)
  - HCPL0452/0500/0501 only



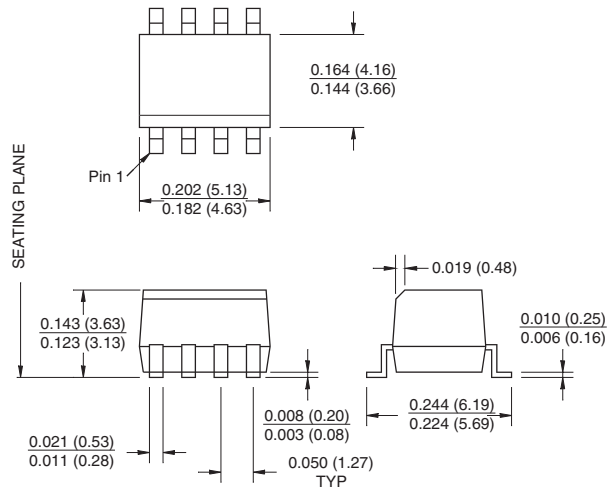
## APPLICATIONS

- Line receivers
- Pulse transformer replacement
- Output interface to CMOS-LSTTL-TTL
- Wide bandwidth analog coupling

## TRUTH TABLE (positive logic)

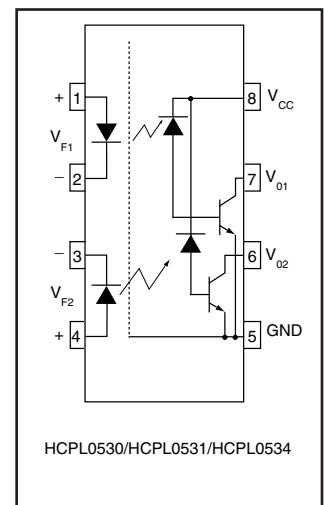
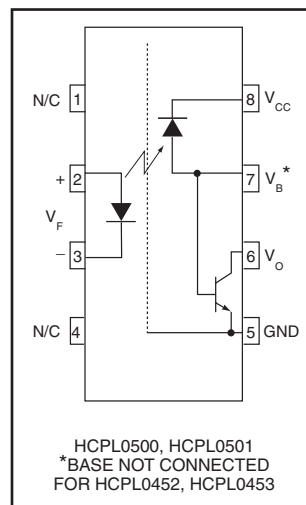
| LED | $V_O$ |
|-----|-------|
| ON  | LOW   |
| OFF | HIGH  |

## PACKAGE DIMENSIONS



### NOTE

All dimensions are in inches (millimeters)



|                        |                 |                 |                 |                 |
|------------------------|-----------------|-----------------|-----------------|-----------------|
| <b>Single Channel:</b> | <b>HCPL0452</b> | <b>HCPL0453</b> | <b>HCPL0500</b> | <b>HCPL0501</b> |
| <b>Dual Channel:</b>   | <b>HCPL0530</b> | <b>HCPL0531</b> | <b>HCPL0534</b> |                 |

**ABSOLUTE MAXIMUM RATINGS** ( $T_A = 25^\circ\text{C}$  unless otherwise specified)

| Parameter                                                            | Symbol           | Value       | Units            |
|----------------------------------------------------------------------|------------------|-------------|------------------|
| Storage Temperature                                                  | $T_{\text{STG}}$ | -40 to +125 | $^\circ\text{C}$ |
| Operating Temperature                                                | $T_{\text{OPR}}$ | -40 to +85  | $^\circ\text{C}$ |
| Reflow Temperature Profile (Refer to page 9)                         |                  |             |                  |
| <b>EMITTER</b>                                                       |                  |             |                  |
| DC/Average Forward Input Current                                     | $I_F$ (avg)      | 25          | mA               |
| Peak Forward Input Current (50% duty cycle, 1 ms P.W.)               | $I_F$ (pk)       | 50          | mA               |
| Peak Transient Input Current - ( $\leq 1 \mu\text{s}$ P.W., 300 pps) | $I_F$ (trans)    | 1.0         | A                |
| Reverse Input Voltage                                                | $V_R$            | 5           | V                |
| Input Power Dissipation                                              | $P_D$            | 45          | mW               |
| <b>DETECTOR</b>                                                      |                  |             |                  |
| Average Output Current (Pin 6)                                       | $I_O$ (avg)      | 8           | mA               |
| Peak Output Current                                                  | $I_O$ (pk)       | 16          | mA               |
| Emitter-Base Reverse Voltage (HCPL0500/HCPL0501 only)                | $V_{\text{EBR}}$ | 5           | V                |
| Supply Voltage                                                       | $V_{\text{CC}}$  | -0.5 to 30  | V                |
| Output Voltage                                                       | $V_O$            | -0.5 to 20  | V                |
| Base Current (HCPL0500/HCPL0501 only)                                | $I_B$            | 5           | mA               |
| Output power dissipation                                             | $P_D$            | 100         | mW               |

**ELECTRICAL CHARACTERISTICS** ( $T_A = 0$  to  $70^\circ\text{C}$  Unless otherwise specified)

**INDIVIDUAL COMPONENT CHARACTERISTICS**

| Parameter                                  | Test Conditions                                                                                  | Symbol                      | Device                  | Min | Typ** | Max | Unit                 |
|--------------------------------------------|--------------------------------------------------------------------------------------------------|-----------------------------|-------------------------|-----|-------|-----|----------------------|
| <b>EMITTER</b>                             |                                                                                                  |                             |                         |     |       |     |                      |
| Input Forward Voltage                      | ( $I_F = 16 \text{ mA}$ , $T_A = 25^\circ\text{C}$ )                                             | $V_F$                       | All                     |     | 1.45  | 1.7 | V                    |
|                                            | ( $I_F = 16 \text{ mA}$ )                                                                        |                             |                         |     |       | 1.8 |                      |
| Input Reverse Breakdown Voltage            | ( $I_R = 10 \mu\text{A}$ )                                                                       | $BV_R$                      | All                     | 5.0 |       |     | V                    |
| Temperature coefficient of forward voltage | ( $I_F = 16 \text{ mA}$ )                                                                        | $(\Delta V_F / \Delta T_A)$ | All                     |     | -1.6  |     | mV/ $^\circ\text{C}$ |
| <b>DETECTOR</b>                            |                                                                                                  |                             |                         |     |       |     |                      |
| Logic high output current                  | ( $I_F = 0 \text{ mA}$ , $V_O = V_{\text{CC}} = 5.5 \text{ V}$ )<br>( $T_A = 25^\circ\text{C}$ ) | $I_{\text{OH}}$             | All                     |     | 0.001 | 0.5 | $\mu\text{A}$        |
|                                            | ( $I_F = 0 \text{ mA}$ , $V_O = V_{\text{CC}} = 15 \text{ V}$ )<br>( $T_A = 25^\circ\text{C}$ )  |                             | All                     |     | 0.005 | 1   |                      |
|                                            | ( $I_F = 0 \text{ mA}$ , $V_O = V_{\text{CC}} = 15 \text{ V}$ )                                  |                             | All                     |     |       | 50  |                      |
| Logic low supply current                   | ( $I_F = 16 \text{ mA}$ , $V_O = \text{Open}$ )<br>( $V_{\text{CC}} = 15 \text{ V}$ )            | $I_{\text{CCL}}$            | HCPL0452/3/<br>0500/1/4 |     | 120   | 200 | $\mu\text{A}$        |
|                                            |                                                                                                  |                             | HCPL0530/1              |     |       | 400 |                      |

Single Channel: HCPL0452 HCPL0453 HCPL0500 HCPL0501  
Dual Channel: HCPL0530 HCPL0531 HCPL0534

**ELECTRICAL CHARACTERISTICS** ( $T_A = 0$  to  $70^\circ\text{C}$  Unless otherwise specified) (Continued)

**INDIVIDUAL COMPONENT CHARACTERISTICS**

| Parameter                 | Test Conditions                                                                           | Symbol    | Device                | Min | Typ** | Max | Unit          |
|---------------------------|-------------------------------------------------------------------------------------------|-----------|-----------------------|-----|-------|-----|---------------|
| Logic high supply current | $(I_F = 0 \text{ mA}, V_O = \text{Open}, V_{CC} = 15 \text{ V}) (T_A = 25^\circ\text{C})$ | $I_{CCH}$ | All                   |     | 0.01  | 1   | $\mu\text{A}$ |
|                           | $(I_F = 0 \text{ mA}, V_O = \text{Open}) (V_{CC} = 15 \text{ V})$                         |           | HCPL0452/3/<br>0500/1 |     |       | 2   |               |
|                           |                                                                                           |           | HCPL0530/1/4          |     |       | 4   |               |

**TRANSFER CHARACTERISTICS** ( $T_A = 0$  to  $70^\circ\text{C}$  Unless otherwise specified)

| Parameter                                                | Test Conditions                                                                                                                                                                                                                                                                                                                                                        | Symbol          | Device               | Min | Typ** | Max | Unit |
|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------|-----|-------|-----|------|
| <b>COUPLED</b><br><br>Current transfer ratio<br>(Note 1) | $(I_F = 16\text{ mA}, V_O = 0.4\text{ V})$<br>$(V_{CC} = 4.5\text{ V}, T_A = 25^\circ\text{C})$<br><br>$(I_F = 16\text{ mA}, V_O = 0.5\text{ V})$<br>$(V_{CC} = 4.5\text{ V})$                                                                                                                                                                                         | CTR             | HCPL0500/0530        | 7   | 27    | 50  | %    |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0452/3           | 19  | 27    | 50  |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0501/0531        |     |       |     |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0500             | 5   | 30    |     |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0452/3           | 15  | 30    |     |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0501/0534        |     |       |     |      |
| Logic low output voltage<br>output voltage               | $(I_F = 16\text{ mA}, I_O = 1.1\text{ mA})$<br>$(V_{CC} = 4.5\text{ V}, T_A = 25^\circ\text{C})$<br><br>$(I_F = 16\text{ mA}, I_O = 3\text{ mA})$<br>$(V_{CC} = 4.5\text{ V}, T_A = 25^\circ\text{C})$<br><br>$(I_F = 16\text{ mA}, I_O = 0.8\text{ mA})$<br>$(V_{CC} = 4.5\text{ V})$<br><br>$(I_F = 16\text{ mA}, I_O = 2.4\text{ mA})$<br>$(V_{CC} = 4.5\text{ V})$ | V <sub>OL</sub> | HCPL0500             |     | 0.18  | 0.4 | V    |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0530             |     |       | 0.5 |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0452/3           |     | 0.25  | 0.4 |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0501/0531/4      |     |       |     |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0500<br>HCPL0530 |     | 0.13  | 0.5 |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0452/3           |     | 0.23  | 0.5 |      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                        |                 | HCPL0501/0531/4      |     |       |     |      |

\*\* All typicals at  $T_A = 25^\circ\text{C}$

|                        |                 |                 |                 |                 |
|------------------------|-----------------|-----------------|-----------------|-----------------|
| <b>Single Channel:</b> | <b>HCPL0452</b> | <b>HCPL0453</b> | <b>HCPL0500</b> | <b>HCPL0501</b> |
| <b>Dual Channel:</b>   | <b>HCPL0530</b> | <b>HCPL0531</b> | <b>HCPL0534</b> |                 |

| <b>SWITCHING CHARACTERISTICS</b> ( $T_A = 0$ to $70^\circ\text{C}$ unless otherwise specified., $V_{CC} = 5\text{ V}$ ) |                                                                                                                                      |            |                 |        |        |     |                        |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------|--------|--------|-----|------------------------|
| Parameter                                                                                                               | Test Conditions                                                                                                                      | Symbol     | Device          | Min    | Typ**  | Max | Unit                   |
| Propagation delay time to logic low                                                                                     | $T_A = 25^\circ\text{C}$ , ( $R_L = 4.1\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 2) (Fig. 9)                                   | $T_{PHL}$  | HCPL0500/0530   |        | 0.45   | 1.5 | $\mu\text{s}$          |
|                                                                                                                         | ( $R_L = 1.9\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 3) (Fig. 9)                                                              |            | HCPL0452/3      |        | 0.45   | 0.8 |                        |
|                                                                                                                         | $T_A = 25^\circ\text{C}$                                                                                                             |            | HCPL0501/0531/4 |        |        |     |                        |
|                                                                                                                         | ( $R_L = 4.1\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 2) (Fig. 9)                                                              |            | HCPL0500/0530   |        |        | 2.0 |                        |
|                                                                                                                         | ( $R_L = 1.9\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 3) (Fig. 9)                                                              |            | HCPL0452/3      |        |        | 1.0 |                        |
|                                                                                                                         |                                                                                                                                      |            | HCPL0501/0531/4 |        |        |     |                        |
| Propagation delay time to logic high                                                                                    | $T_A = 25^\circ\text{C}$ , ( $R_L = 4.1\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 2) (Fig. 9)                                   | $T_{PLH}$  | HCPL0500/0530   |        | 0.5    | 1.5 | $\mu\text{s}$          |
|                                                                                                                         | ( $R_L = 1.9\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 3) (Fig. 9)                                                              |            | HCPL0452/3      |        | 0.3    | 0.8 |                        |
|                                                                                                                         | $T_A = 25^\circ\text{C}$                                                                                                             |            | HCPL0501/0531/4 |        |        |     |                        |
|                                                                                                                         | ( $R_L = 4.1\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 2) (Fig. 9)                                                              |            | HCPL0500/0530   |        |        | 2.0 |                        |
|                                                                                                                         | ( $R_L = 1.9\text{ k}\Omega$ , $I_F = 16\text{ mA}$ ) (Note 3) (Fig. 9)                                                              |            | HCPL0452/3      |        |        | 1.0 |                        |
|                                                                                                                         |                                                                                                                                      |            | HCPL0501/0531/4 |        |        |     |                        |
| Common mode transient immunity at logic high                                                                            | ( $I_F = 0\text{ mA}$ , $V_{CM} = 10\text{ V}_{P-P}$ , $R_L = 4.1\text{ k}\Omega$ ) (Note 4) (Fig. 10) $T_A = 25^\circ\text{C}$      | $ICM_{HI}$ | HCPL0500        | 1,000  | 10,000 |     | $\text{V}/\mu\text{s}$ |
|                                                                                                                         |                                                                                                                                      |            | HCPL0530        |        |        |     |                        |
|                                                                                                                         | ( $I_F = 0\text{ mA}$ , $V_{CM} = 10\text{ V}_{P-P}$ ) $T_A = 25^\circ\text{C}$ , ( $R_L = 1.9\text{ k}\Omega$ ) (Note 4) (Fig. 10)  |            | HCPL0452        | 1,000  | 10,000 |     |                        |
|                                                                                                                         |                                                                                                                                      |            | HCPL0501/31     |        |        |     |                        |
|                                                                                                                         | ( $I_F = 16\text{ mA}$ , $V_{CM} = 1500\text{ V}_{P-P}$ , $R_L = 1.9\Omega$ , $T_A = 25^\circ\text{C}$ ) (note 4) (Fig. 10)          |            | HCPL0534        | 15,000 | 40,000 |     |                        |
|                                                                                                                         |                                                                                                                                      |            | HCPL0453        | 15,000 | 40,000 |     |                        |
| Common mode transient immunity at logic low                                                                             | ( $I_F = 16\text{ mA}$ , $V_{CM} = 10\text{ V}_{P-P}$ , $R_L = 4.1\text{ k}\Omega$ ) (Note 4) (Fig. 10) $T_A = 25^\circ\text{C}$     | $ICM_{LI}$ | HCPL0500        | 1,000  | 10,000 |     | $\text{V}/\mu\text{s}$ |
|                                                                                                                         |                                                                                                                                      |            | HCPL0530        |        |        |     |                        |
|                                                                                                                         | ( $I_F = 16\text{ mA}$ , $V_{CM} = 10\text{ V}_{P-P}$ ) $T_A = 25^\circ\text{C}$ , ( $R_L = 1.9\text{ k}\Omega$ ) (Note 4) (Fig. 10) |            | HCPL0452        | 1,000  | 10,000 |     |                        |
|                                                                                                                         |                                                                                                                                      |            | HCPL0501/31     |        |        |     |                        |
|                                                                                                                         | ( $I_F = 16\text{ mA}$ , $T_A = 25^\circ\text{C}$ , $V_{CM} = 1500\text{ V}_{P-P}$ , $C_L = 15\text{ pF}$ ) (Note 4) (Fig. 10)       |            | HCPL0534        | 15,000 | 40,000 |     |                        |
|                                                                                                                         |                                                                                                                                      |            | HCPL0453        | 15,000 | 40,000 |     |                        |

| <b>ISOLATION CHARACTERISTICS</b> ( $T_A = 0^\circ\text{C}$ to $+70^\circ\text{C}$ Unless otherwise specified.) |                                                                  |           |           |       |     |             |
|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|-----------|-----------|-------|-----|-------------|
| Characteristics                                                                                                | Test Conditions                                                  | Symbol    | Min       | Typ** | Max | Unit        |
| Input-Output Isolation Voltage                                                                                 | (note 5, 6) ( $f = 60\text{ Hz}$ , $t = 1.0\text{ min}$ )        | $V_{ISO}$ | 2500      | —     | —   | $V_{ACRMS}$ |
| Isolation Resistance                                                                                           | (note 5) ( $V_{I-O} = 500\text{ V}$ ) <sup>(9)</sup>             | $R_{ISO}$ | $10^{11}$ | —     | —   | $\Omega$    |
| Isolation Capacitance                                                                                          | (note 5) ( $V_{I-O} = 0$ , $f = 1.0\text{ MHz}$ ) <sup>(9)</sup> | $C_{ISO}$ | —         | 0.2   | —   | $\text{pF}$ |

\*\* All typicals at  $T_A = 25^\circ\text{C}$

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|                        |                 |                 |                 |                 |
|------------------------|-----------------|-----------------|-----------------|-----------------|
| <b>Single Channel:</b> | <b>HCPL0452</b> | <b>HCPL0453</b> | <b>HCPL0500</b> | <b>HCPL0501</b> |
| <b>Dual Channel:</b>   | <b>HCPL0530</b> | <b>HCPL0531</b> | <b>HCPL0534</b> |                 |

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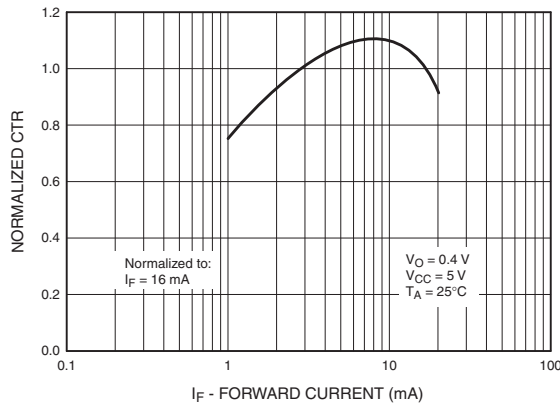
**NOTES**

1. Current Transfer Ratio is defined as a ratio of output collector current,  $I_O$ , to the forward LED input current,  $I_F$  times 100%.
2. The 4.1 k $\Omega$  load represents 1 LSTTL unit load of 0.36 mA and 6.1k $\Omega$  pull-up resistor.
3. The 1.9 k $\Omega$  load represents 1 TTL unit load of 1.6 mA and 5.6 k $\Omega$  pull-up resistor.
4. Common mode transient immunity in logic high level is the maximum tolerable (positive)  $dV_{CM}/dt$  on the leading edge of the common mode pulse signal  $V_{CM}$ , to assure that the output will remain in a logic high state (i.e.,  $V_O > 2.0$  V). Common mode transient immunity in logic low level is the maximum tolerable (negative)  $dV_{CM}/dt$  on the trailing edge of the common mode pulse signal,  $V_{CM}$ , to assure that the output will remain in a logic low state (i.e.,  $V_O < 0.8$  V).
5. Device is considered a two terminal device: Pins 1, 2, 3 and 4 are shorted together and Pins 5, 6, 7 and 8 are shorted together.
6. 2500 VAC RMS for 1 minute duration is equivalent to 3000 VAC RMS for 1 second duration.

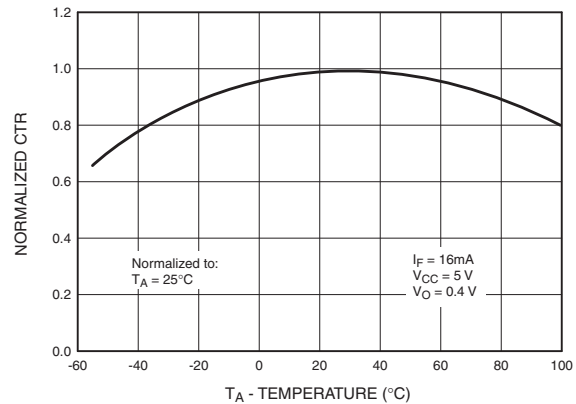
|                 |          |          |          |          |
|-----------------|----------|----------|----------|----------|
| Single Channel: | HCPL0452 | HCPL0453 | HCPL0500 | HCPL0501 |
| Dual Channel:   | HCPL0530 | HCPL0531 | HCPL0534 |          |

**TYPICAL PERFORMANCE CURVES**

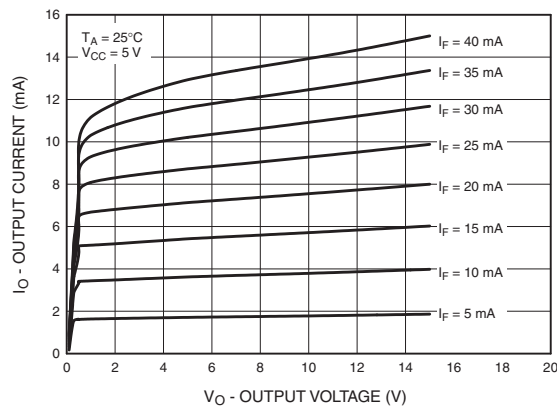
**Fig. 1 Normalized CTR vs. Forward Current**



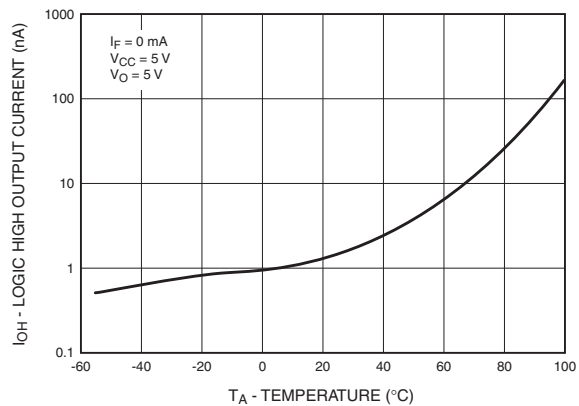
**Fig. 2 Normalized CTR vs. Temperature**



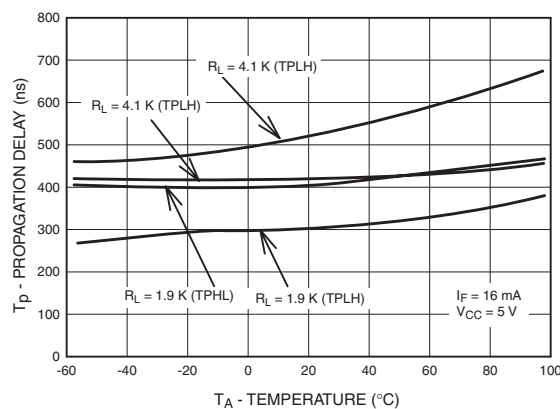
**Fig. 3 Output Current vs. Output Voltage**



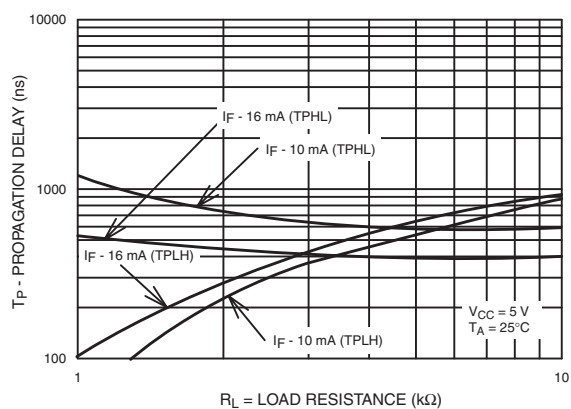
**Fig. 4 Logic High Output Current vs. Temperature**



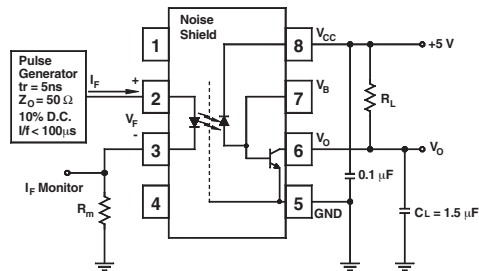
**Fig. 5 Propagation Delay vs. Temperature**



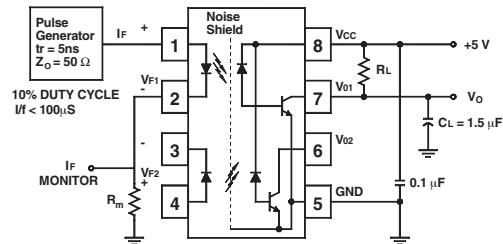
**Fig. 6 Propagation Delay vs. Load Resistance**



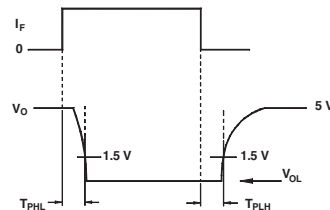
|                 |          |          |          |          |
|-----------------|----------|----------|----------|----------|
| Single Channel: | HCPL0452 | HCPL0453 | HCPL0500 | HCPL0501 |
| Dual Channel:   | HCPL0530 | HCPL0531 | HCPL0534 |          |



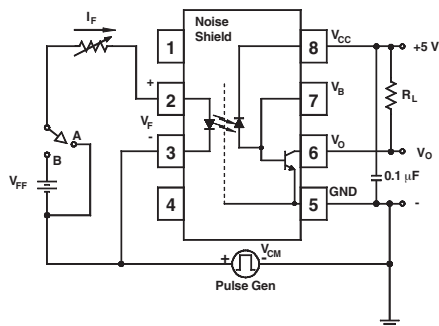
Test Circuit for HCPL0452, HCPL0453, HCPL0500 and HCPL0501



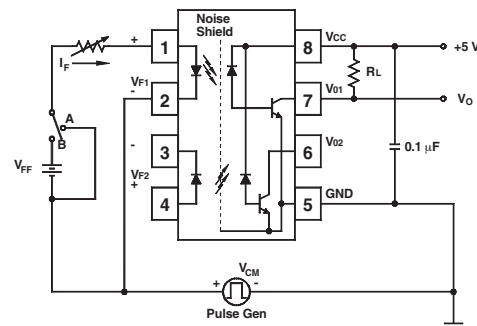
Test Circuit for HCPL0530, HCPL0531 and HCPL0534



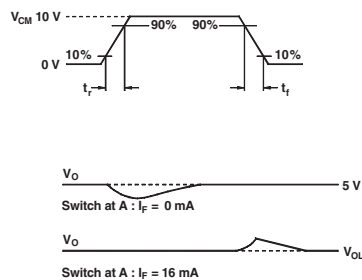
**Fig. 7 Switching Time Test Circuit**



Test Circuit for HCPL0452, HCPL0453, HCPL0500 and HCPL0501



Test Circuit for HCPL0530, HCPL0531 and HCPL0534



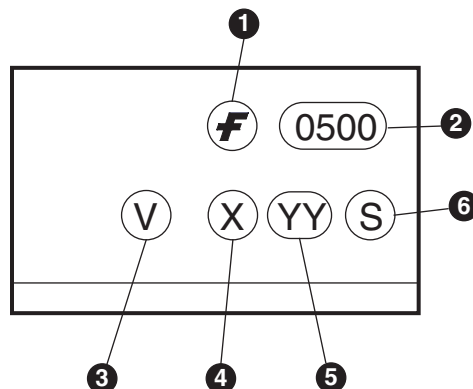
**Fig. 8 Common Mode Immunity Test Circuit**

|                 |          |          |          |          |
|-----------------|----------|----------|----------|----------|
| Single Channel: | HCPL0452 | HCPL0453 | HCPL0500 | HCPL0501 |
| Dual Channel:   | HCPL0530 | HCPL0531 | HCPL0534 |          |

## ORDERING INFORMATION

| Option | Order Entry Identifier | Description                                                                                           |
|--------|------------------------|-------------------------------------------------------------------------------------------------------|
| V      | V                      | VDE 0884 (approval pending for HCPL0530, HCPL0531 & HCPL0534)                                         |
| R1     | R1                     | Tape and reel (500 units per reel)                                                                    |
| R1V    | R1V                    | VDE 0884 (approval pending for HCPL0530, HCPL0531 & HCPL0534),<br>Tape and reel (500 units per reel)  |
| R2     | R2                     | Tape and reel (2500 units per reel)                                                                   |
| R2V    | R2V                    | VDE 0884 (approval pending for HCPL0530, HCPL0531 & HCPL0534),<br>Tape and reel (2500 units per reel) |

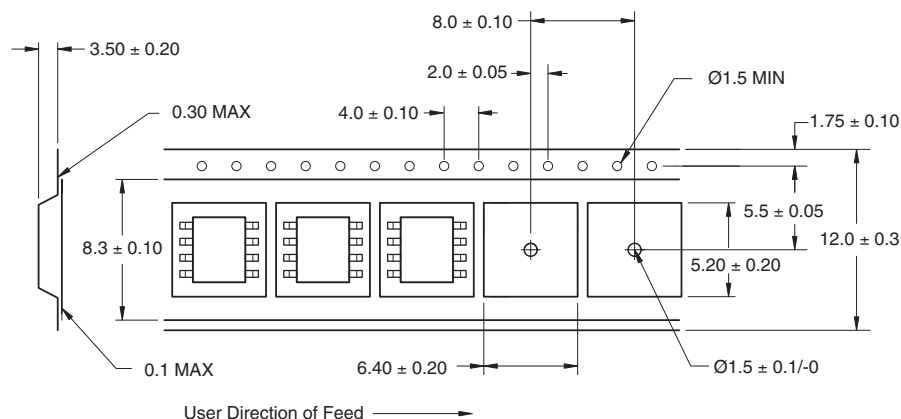
## MARKING INFORMATION



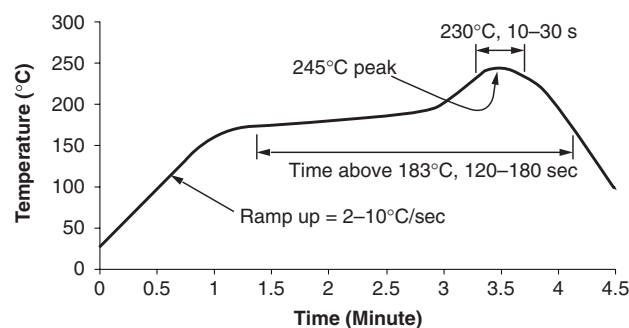
| Definitions |                                                                                        |
|-------------|----------------------------------------------------------------------------------------|
| 1           | Fairchild logo                                                                         |
| 2           | Device number                                                                          |
| 3           | VDE mark (Note: Only appears on parts ordered with VDE option – See order entry table) |
| 4           | One digit year code, e.g., '3'                                                         |
| 5           | Two digit work week ranging from '01' to '53'                                          |
| 6           | Assembly package code                                                                  |

|                 |          |          |          |          |
|-----------------|----------|----------|----------|----------|
| Single Channel: | HCPL0452 | HCPL0453 | HCPL0500 | HCPL0501 |
| Dual Channel:   | HCPL0530 | HCPL0531 | HCPL0534 |          |

## Carrier Tape Specifications



## Reflow Profile



- Peak reflow temperature: 245°C (package surface temperature)
- Time of temperature higher than 183°C for 120–180 seconds
- One time soldering reflow is recommended

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|                        |                 |                 |                 |                 |
|------------------------|-----------------|-----------------|-----------------|-----------------|
| <b>Single Channel:</b> | <b>HCPL0452</b> | <b>HCPL0453</b> | <b>HCPL0500</b> | <b>HCPL0501</b> |
| <b>Dual Channel:</b>   | <b>HCPL0530</b> | <b>HCPL0531</b> | <b>HCPL0534</b> |                 |

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2. A critical component in any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.